

SUBCHAPTER H—MEDICAL DEVICES

PART 800—GENERAL

Subpart A [Reserved]

Subpart B—Requirements for Specific Medical Devices

Sec.

800.10 Contact lens solution; sterility.

800.12 Contact lens solutions and tablets; tamper-resistant packaging.

800.20 Patient examination gloves and surgeons' gloves; sample plans and test method for leakage defects; adulteration.

Subpart C—Administrative Practices and Procedures

800.55 Administrative detention.

AUTHORITY: Secs. 201, 304, 501, 502, 505, 506, 507, 515, 519, 521, 601, 602, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 334, 351, 352, 355, 356, 357, 360e, 360i, 360k, 361, 362, 371).

Subpart A [Reserved]

Subpart B—Requirements for Specific Medical Devices

§800.10 Contact lens solutions; sterility.

(a)(1) Informed medical opinion is in agreement that all preparations offered or intended for ophthalmic use, including contact lens solutions, should be sterile. It is further evident that such preparations purport to be of such purity and quality as to be suitable for safe use in the eye.

(2) The Food and Drug Administration concludes that all such preparations, if they are not sterile, fall below their professed standard of purity or quality and may be unsafe. In a statement of policy issued on September 1, 1964, the Food and Drug Administration ruled that liquid preparations offered or intended for ophthalmic use that are not sterile may be regarded as adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act (the act), and, further, may be deemed misbranded within the meaning of section 502(j) of the act. By this regulation, this ruling is applicable to all preparations for oph-

thalmic use that are regulated as medical devices, i.e., contact lens solutions. By the regulation in §200.50 of this chapter, this ruling is applicable to ophthalmic preparations that are regulated as drugs.

(3) The containers shall be sterile at the time of filling and closing, and the container or individual carton shall be so sealed that the contents cannot be used without destroying the seal. The packaging and labeling of these solutions shall also comply with §800.12 on tamper-resistant packaging requirements.

(b) Liquid ophthalmic preparations packed in multiple-dose containers should:

(1) Contain one or more suitable and harmless substances that will inhibit the growth of microorganisms; or

(2) Be so packaged as to volume and type of container and so labeled as to duration of use and with such necessary warnings as to afford adequate protection and minimize the hazard of injury resulting from contamination during use.

(c) Eye cups, eye droppers, and other dispensers intended for ophthalmic use should be sterile, and may be regarded as falling below their professed standard of purity or quality if they are not sterile. These articles, which are regulated as medical devices unless packaged with the drugs with which they are to be used, should be packaged so as to maintain sterility until the package is opened and be labeled, on or within the retail package, so as to afford adequate directions and necessary warnings to minimize the hazard of injury resulting from contamination during use.

[47 FR 50455, Nov. 5, 1982]

§800.12 Contact lens solutions and tablets; tamper-resistant packaging.

(a) *General.* Unless contact lens solutions used, for example, to clean, disinfect, wet, lubricate, rinse, soak, or store contact lenses and salt tablets or other dosage forms to be used to make any such solutions are packaged in tamper-resistant retail packages, there

is the opportunity for the malicious adulteration of these products with risks both to individuals who unknowingly purchase adulterated products and with loss of consumer confidence in the security of the packages of over-the-counter (OTC) health care products. The Food and Drug Administration has the authority and responsibility under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national standard for tamper-resistant packaging of those OTC products vulnerable to malicious adulteration that will improve the security of OTC packaging and help assure the safety and effectiveness of the products contained therein. A contact lens solution or tablet or other dosage form to be used to make such a solution for retail sale that is not packaged in a tamper-resistant package and labeled in accordance with this section is adulterated under section 501 of the act or misbranded under section 502 of the act, or both.

(b) *Requirement for tamper-resistant package.* Each manufacturer and packer who packages for retail sale a product regulated as a medical device that is a solution intended for use with contact lenses, e.g., for cleaning, disinfecting, wetting, lubricating, rinsing, soaking, or storing contact lenses or tablets or other dosage forms to be used to make any such solution shall package the product in a tamper-resistant package, if this product is accessible to the public while held for sale. A tamper-resistant package is one having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of substitution of a tamper-resistant feature after tampering, the indicator or barrier to entry is required to be distinctive by design or by the use of an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of this section, the term “distinctive by design” means the package cannot be duplicated with commonly available material or through commonly available processes. A tamper-resistant package may involve an immediate-container and closure system or secondary-container or

carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(c) *Labeling.* Each retail package of a product covered by this section is required to bear a statement that is prominently placed so that consumers are alerted to the tamper-resistant feature of the package. The labeling statement is also required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper-resistant feature chosen to meet the requirement in paragraph (b) of this section is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say “For your protection, this bottle has an imprinted seal around the neck.”

(d) *Requests for exemptions from packaging and labeling requirements.* A manufacturer or packer may request an exemption from the packaging and labeling requirements of this section. A request for an exemption is required to be submitted in the form of a citizen petition under §10.30 of this chapter and should be clearly identified on the envelope as a “Request for Exemption from Tamper-resistant Rule.” A petition for an exemption from a requirement of this section is required to contain the same kind of information about the product as is specified for OTC drugs in §211.132(d) of this chapter. This information collection requirement has been approved by the Office of Management and Budget under number 0910-0150.

(e) *Products subject to approved premarket approval applications.* Holders of approved premarket approval applications for products subject to this section are required to submit supplements to provide for changes in packaging to comply with the requirement of paragraph (b) of this section unless these changes do not affect the composition of the container, the torque (tightness) of the container, or the

composition of the closure component in contact with the contents (cap liner or innerseal) as these features are described in the approved premarket approval application. Any supplemental premarket approval application under this paragraph is required to include data sufficient to show that these changes do not adversely affect the product.

(f) *Effective date.* Each product subject to this section is required to comply with the requirements of this section on the dates listed below except to the extent that a product's manufacturer or packer has obtained an exemption from a packaging or labeling requirement:

(1) *Initial effective date for packaging requirements.* (i) The packaging requirement in paragraph (b) of this section is effective on February 7, 1983 for each contact lens solution packaged for retail sale on or after that date, except for the requirement in paragraph (b) of this section for a distinctive indicator or barrier to entry.

(ii) The packaging requirement in paragraph (b) of this section is effective on May 5, 1983 for each tablet that is to be used to make a contact lens solution and that is packaged for retail sale on or after that date.

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each product subject to this section packaged for retail sale on or after that date, except that the requirement for a specific label reference to any identifying characteristic is effective on February 6, 1984 for each affected product subject to this section packaged for retail sale on or after that date.

(3) *Retail level effective date.* The tamper-resistant packaging requirement of paragraph (b) of this section is effective on February 6, 1984 for each product subject to this section that is held for sale at retail level on or after that date that was packaged for retail sale before May 5, 1983. This does not include the requirement in paragraph (b) of this section that the indicator or

barrier to entry be distinctive by design. Products packaged for retail sale after May 5, 1983, are required to be in compliance with all aspects of the regulations without regard to the retail level effective date.

[47 FR 50455, Nov. 5, 1982; 48 FR 1706, Jan. 14, 1983, as amended at 48 FR 16666, Apr. 19, 1983; 48 FR 37625, Aug. 19, 1983; 53 FR 11252, Apr. 6, 1988]

EFFECTIVE DATE NOTE: A document published at 48 FR 41579, Sept. 16, 1983, stayed the effective date of § 800.12(f)(3) until further notice.

§ 800.20 Patient examination gloves and surgeons' gloves; sample plans and test method for leakage defects; adulteration.

(a) *Purpose.* The prevalence of human immunodeficiency virus (HIV), which causes acquired immune deficiency syndrome (AIDS), and its risk of transmission in the health care context, have caused the Food and Drug Administration (FDA) to look more closely at the quality control of barrier devices, such as surgeons' gloves and patient examination gloves (collectively known as medical gloves) to reduce the risk of transmission of HIV and other blood-borne infectious diseases. The Centers for Disease Control (CDC) recommend that health care workers wear medical gloves to reduce the risk of transmission of HIV and other blood-borne infectious diseases. The CDC recommends that health care workers wear medical gloves when touching blood or other body fluids, mucous membranes, or nonintact skin of all patients; when handling items or surfaces soiled with blood or other body fluids; and when performing venipuncture and other vascular access procedures. Among other things, CDC's recommendation that health care providers wear medical gloves demonstrates the proposition that devices labeled as medical gloves purport to be and are represented to be effective barriers against the transmission of blood- and fluid-borne pathogens. Therefore, FDA, through this regulation, is defining adulteration for patient examination and surgeons' gloves as a means of assuring safe and effective devices.

(1) For a description of a patient examination glove, see § 880.6250. Finger

cots, however, are excluded from the test method and sample plans in paragraphs (b) and (c) of this section.

(2) For a description of a surgeons' glove, see § 878.4460 of this chapter.

(b) *Test method.* For the purposes of this regulation, FDA's analysis of gloves for leaks will be conducted by a water leak method, using 1,000 milliliters (mL) of water. Each medical glove will be analyzed independently. When packaged as pairs, each glove is considered separately, and both gloves will be analyzed. A defect on one of the gloves is counted as one defect; a defect in both gloves is counted as two defects. Defects are defined as leaks, tears, mold, embedded foreign objects, etc. A leak is defined as the appearance of water on the outside of the glove. This emergence of water from the glove constitutes a watertight barrier failure. Leaks within 1 and ½ inches of the cuff are to be disregarded.

(1) The following materials are required for testing: A 2¾-inch by 15-inch (clear) plastic cylinder with a hook on one end and a mark scored 1½ inches from the other end (a cylinder of another size may be used if it accommodates both cuff diameter and any water above the glove capacity); elastic strapping with velcro or other fastening material; automatic water-dispensing apparatus or manual device capable of delivering 1,000 mL of water; a stand with horizontal rod for hanging the hook end of the plastic tube. The support rod must be capable of holding the weight of the total number of gloves that will be suspended at any one time, e.g., five gloves suspended will weigh about 11 pounds.

(2) The following methodology is used: Examine the sample and identify code/ lot number, size, and brand as appropriate. Examine gloves for defects as follows: carefully remove the glove from the wrapper, box, etc., visually examining each glove for defects. Visual defects in the top 1½ inches of a glove will not be counted as a defect for the purposes of this rule. Visually defective gloves do not require further testing but are to be included in the

total number of defective gloves counted for the sample. Attach the glove to the plastic fill tube by bringing the cuff end to the 1½-inch mark and fastening with elastic strapping to make a watertight seal. Add 1,000 mL of room temperature water (i.e., 20 °C to 30 °C) into the open end of the fill tube. The water shall pass freely into the glove. (With some larger sizes of long-cuffed surgeons' gloves, the water level may reach only the base of the thumb. With some smaller gloves, the water level may extend several inches up the fill tube.)

(3) Immediately after adding the water, examine the glove for water leaks. Do not squeeze the glove; use only minimal manipulation to spread the fingers to check for leaks. Water drops may be blotted to confirm leaking. If the glove does not leak immediately, keep the glove/filling tube assembly upright and hang the assembly vertically from the horizontal rod, using the wire hook on the open end of the fill tube (do not support the filled glove while transferring). Make a second observation for leaks 2 minutes after addition of the water to the glove. Use only minimal manipulation of the fingers to check for leaks. Record the number of defective gloves.

(c) *Sample plans.* FDA will collect samples from lots of gloves to perform the test for defects described in paragraph (b) of this section in accordance with FDA's sampling inspection plans which are based on the tables of MIL-STD-105E (the military sampling standard, "Sampling Procedures and Tables for Inspection by Attributes," May 10, 1989). Based on the acceptable quality levels found in this standard, FDA has defined adulteration as follows: 2.5 or higher for surgeons' gloves and 4.0 or higher for patient examination gloves at a general inspection level II. FDA will use single normal sampling for lots of 1,200 gloves or less and multiple normal sampling for all larger lots. For convenience, the sample plans (sample size and accept/reject numbers) are shown in the following tables:

ADULTERATION LEVEL AT 2.5 FOR SURGEONS' GLOVES

Lot size	Sample	Sample size	Number examined	Number defective	
				Accept	Reject
35,001 and above	First	125	125	2	9
	Second	125	250	7	14
	Third	125	375	13	19
	Fourth	125	500	19	25
	Fifth	125	625	25	29
	Sixth	125	750	31	33
	Seventh	125	875	37	38
35,000 to 10,001	First	80	80	1	7
	Second	80	160	4	10
	Third	80	240	8	13
	Fourth	80	320	12	17
	Fifth	80	400	17	20
	Sixth	80	480	21	23
	Seventh	80	560	25	26
10,000 to 3,201	First	50	50	0	5
	Second	50	100	3	8
	Third	50	150	6	10
	Fourth	50	200	8	13
	Fifth	50	250	11	15
	Sixth	50	300	14	17
	Seventh	50	350	18	19
3,200 to 1,201	First	32	32	0	4
	Second	32	64	1	6
	Third	32	96	3	8
	Fourth	32	128	5	10
	Fifth	32	160	7	11
	Sixth	32	192	10	12
	Seventh	32	224	13	14
1,200 to 501	Single sample	80	5	6
500 to 281	Single sample	50	3	4
280 to 151	Single sample	32	2	3
150 to 51	Single sample	20	1	2
50 to 0	Single sample	5	0	1

ADULTERATION LEVEL AT 4.0 FOR PATIENT EXAMINATION GLOVES

Lot size	Sample	Sample size	Number examined	Number defective	
				Accept	Reject
10,001 and above	First	80	80	2	9
	Second	80	160	7	14
	Third	80	240	13	19
	Fourth	80	320	19	25
	Fifth	80	400	25	29
	Sixth	80	480	31	33
	Seventh	80	560	37	38
10,000 to 3,201	First	50	50	1	7
	Second	50	100	4	10
	Third	50	150	8	13
	Fourth	50	200	12	17
	Fifth	50	250	17	20
	Sixth	50	300	21	23
	Seventh	50	350	25	26
3,200 to 1,201	First	32	32	0	5
	Second	32	64	3	8
	Third	32	96	6	10
	Fourth	32	128	8	13
	Fifth	32	160	11	15
	Sixth	32	192	14	17
	Seventh	32	224	18	19
1,200 to 501	Single sample	80	7	8
500 to 281	Single sample	50	5	6
280 to 151	Single sample	32	3	4
150 to 91	Single sample	20	2	3
90 to 26	Single sample	13	1	2
25 to 0	Single sample	3	0	1

(d) Lots of gloves which are tested and rejected using the test method according to paragraph (b) of this section, are adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act, and are subject to regulatory action, such as detention of imported products and seizure of domestic products.

[55 FR 51256, Dec. 12, 1990]

Subpart C—Administrative Practices and Procedures

§ 800.55 Administrative detention.

(a) *General.* This section sets forth the procedures for detention of medical devices intended for human use believed to be adulterated or misbranded. Administrative detention is intended to protect the public by preventing distribution or use of devices encountered during inspections that may be adulterated or misbranded, until the Food and Drug Administration (FDA) has had time to consider what action it should take concerning the devices, and to initiate legal action, if appropriate. Devices that FDA orders detained may not be used, moved, altered, or tampered with in any manner by any person during the detention period, except as authorized under paragraph (h) of this section, until FDA terminates the detention order under paragraph (j) of this section, or the detention period expires, whichever occurs first.

(b) *Criteria for ordering detention.* Administrative detention of devices may be ordered in accordance with this section when an authorized FDA representative, during an inspection under section 704 of the Federal Food, Drug, and Cosmetic Act (the act), has reason to believe that a device, as defined in section 201(h) of the act, is adulterated or misbranded.

(c) *Detention period.* The detention is to be for a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless the FDA District Director in whose district the devices are located determines that a greater period is required to seize the devices, to institute injunction proceedings, or to evaluate the need for legal action, in which case the District Di-

rector may authorize detention for 10 additional calendar days. The additional 10-calendar-day detention period may be ordered at the time the detention order is issued or at any time thereafter. The entire detention period may not exceed 30 calendar days, except when the detention period is extended under paragraph (g)(6) of this section. An authorized FDA representative may, in accordance with paragraph (j) of this section, terminate a detention before the expiration of the detention period.

(d) *Issuance of detention order.* (1) The detention order shall be issued in writing, in the form of a detention notice, signed by the authorized FDA representative who has reason to believe that the devices are adulterated or misbranded, and issued to the owner, operator, or agent in charge of the place where the devices are located. If the owner or the user of the devices is different from the owner, operator, or agent in charge of the place where the devices are detained, a copy of the detention order shall be provided to the owner or user of the devices if the owner's or user's identity can be readily determined.

(2) If detention of devices in a vehicle or other carrier is ordered, a copy of the detention order shall be provided to the shipper of record and the owner of the vehicle or other carrier, if their identities can be readily determined.

(3) The detention order shall include the following information: (i) A statement that the devices identified in the order are detained for the period shown; (ii) a brief, general statement of the reasons for the detention; (iii) the location of the devices; (iv) a statement that these devices are not to be used, moved, altered, or tampered with in any manner during that period, except as permitted under paragraph (h) of this section, without the written permission of an authorized FDA representative; (v) identification of the detained devices; (vi) the detention order number; (vii) the date and hour of the detention order; (viii) the period of the detention; (ix) the text of section 304(g) of the act and paragraph (g) (1) and (2) of this section; (x) a statement that any informal hearing on an appeal of a detention order shall be conducted as a

regulatory hearing under part 16 of this chapter, with certain exceptions described in paragraph (g)(3) of this section; and (xi) the location and telephone number of the FDA district office and the name of the FDA District Director.

(e) *Approval of detention order.* A detention order, before issuance, shall be approved by the FDA District Director in whose district the devices are located. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written memorandum within FDA as soon as possible.

(f) *Labeling or marking a detained device.* An FDA representative issuing a detention order under paragraph (d) of this section shall label or mark the devices with official FDA tags that include the following information:

(1) A statement that the devices are detained by the United States Government in accordance with section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)).

(2) A statement that the devices shall not be used, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative, except as authorized in paragraph (h) of this section.

(3) A statement that the violation of a detention order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 303 of the act, 21 U.S.C. 333).

(4) The detention order number, the date and hour of the detention order, the detention period, and the name of the FDA representative who issued the detention order.

(g) *Appeal of a detention order.* (1) A person who would be entitled to claim the devices, if seized, may appeal a detention order. Any appeal shall be submitted in writing to the FDA District Director in whose district the devices are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in section 201(y) of the act, the appellant shall request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which shall not be later than 20

calendar days after receipt of a detention order.

(2) The appellant of a detention order shall state the ownership or proprietary interest the appellant has in the detained devices. If the detained devices are located at a place other than an establishment owned or operated by the appellant, the appellant shall include documents showing that the appellant would have legitimate authority to claim the devices if seized.

(3) Any informal hearing on an appeal of a detention order shall be conducted as a regulatory hearing pursuant to regulation in accordance with part 16 of this chapter, except that:

(i) The detention order under paragraph (d) of this section, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(ii) A request for a hearing under this section should be addressed to the FDA District Director.

(iii) The last sentence of § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this section.

(iv) Paragraph (g)(4) of this section, rather than § 16.42(a) of this chapter, describes the FDA employees, i.e., regional food and drug directors, who preside at hearings under this section.

(4) The presiding officer of a regulatory hearing on an appeal of a detention order, who also shall decide the appeal, shall be a regional food and drug director (i.e., a director of an FDA regional office listed in § 5.115 of this chapter) who is permitted by § 16.42(a) of this chapter to preside over the hearing.

(5) If the appellant requests a regulatory hearing and requests that the hearing be held within 5 working days after the appeal is filed, the presiding officer shall, within 5 working days, hold the hearing and render a decision affirming or revoking the detention.

(6) If the appellant requests a regulatory hearing and requests that the hearing be held at a date later than

within 5 working days after the appeal is filed, but not later than 20 calendar days after receipt of a detention order, the presiding officer shall hold the hearing at a date agreed upon by FDA and the appellant. The presiding officer shall decide whether to affirm or revoke the detention within 5 working days after the conclusion of the hearing. The detention period extends to the date of the decision even if the 5-working-day period for making the decision extends beyond the otherwise applicable 20-calendar-day or 30-calendar-day detention period.

(7) If the appellant appeals the detention order but does not request a regulatory hearing, the presiding officer shall render a decision on the appeal affirming or revoking the detention within 5 working days after the filing of the appeal.

(8) If the presiding officer affirms a detention order, the devices continue to be detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(9) If the presiding officer revokes a detention order, FDA shall terminate the detention under paragraph (j) of this section.

(h)(1) *Movement of detained devices.* Except as provided in this paragraph, no person shall move detained devices within or from the place where they have been ordered detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(2) If detained devices are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work needed to put them in final form. As soon as the devices are moved for this purpose, the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or another responsible district office official, of the movement of the devices. As soon as the devices are put in final form, they shall be segregated from other devices, and the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or an-

other responsible district office official, of their new location. The devices put in final form shall not be moved further without FDA approval.

(3) The FDA representative who issued the detention order, or another responsible district office official, may approve, in writing, the movement of detained devices for any of the following purposes:

(i) To prevent interference with an establishment's operations or harm to the devices.

(ii) To destroy the devices.

(iii) To bring the devices into compliance.

(iv) For any other purpose that the FDA representative who issued the detention order, or other responsible district office official, believes is appropriate in the case.

(4) If an FDA representative approves the movement of detained devices under paragraph (h)(3) of this section, the detained devices shall remain segregated from other devices and the person responsible for their movement shall immediately orally notify the official who approved the movement of the devices, or another responsible FDA district office official, of the new location of the detained devices.

(5) Unless otherwise permitted by the FDA representative who is notified of, or who approves, the movement of devices under this paragraph, the required tags shall accompany the devices during and after movement and shall remain with the devices until FDA terminates the detention or the detention period expires, whichever occurs first.

(i) *Actions involving adulterated or misbranded devices.* If FDA determines that the detained devices, including any that have been put in final form, are adulterated or misbranded, or both, it may initiate legal action against the devices or the responsible individuals, or both, or request that the devices be destroyed or otherwise brought into compliance with the act under FDA's supervision.

(j) *Detention termination.* If FDA decides to terminate a detention or when the detention period expires, whichever occurs first, an FDA representative authorized to terminate a detention will issue a detention termination notice

releasing the devices to any person who received the original detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags.

(k) *Recordkeeping requirements.* (1) After issuance of a detention order under paragraph (d) of this section, the owner, operator, or agent in charge of any factory, warehouse, other establishment, or consulting laboratory where detained devices are manufactured, processed, packed, or held shall have, or establish, and maintain adequate records relating to how the detained devices may have become adulterated or misbranded, records on any distribution of the devices before and after the detention period, records on the correlation of any in-process detained devices that are put in final form under paragraph (h) of this section to the completed devices, records of any changes in, or processing of, the devices permitted under the detention order, and records of any other movement under paragraph (h) of this section. Records required under this paragraph shall be provided to the FDA on request for review and copying. Any FDA request for access to records required under this paragraph shall be made at a reasonable time, shall state the reason or purpose for the request, and shall identify to the fullest extent practicable the information or type of information sought in the records to which access is requested.

(2) Records required under this paragraph shall be maintained for a maximum period of 2 years after the issuance of the detention order or for such other shorter period as FDA directs. When FDA terminates the detention or when the detention period expires, whichever occurs first, FDA will advise all persons required under this paragraph to keep records concerning that detention whether further recordkeeping is required for the remainder of the 2-year, or shorter, period. FDA ordinarily will not require further recordkeeping if the agency determines that the devices are not adulterated or misbranded or that recordkeeping is not necessary to protect the public health, unless the records are required under other regulations in this chapter

(e.g., the good manufacturing practice regulation in part 820 of this chapter).

[44 FR 13239, Mar. 9, 1979, as amended at 49 FR 3174, Jan. 26, 1984]

PART 801—LABELING

Subpart A—General Labeling Provisions

Sec.

801.1 Medical devices; name and place of business of manufacturer, packer or distributor.

801.4 Meaning of "intended uses."

801.5 Medical devices; adequate directions for use.

801.6 Medical devices; misleading statements.

801.15 Medical devices; prominence of required label statements.

801.16 Medical devices; Spanish-language version of certain required statements.

Subpart B [Reserved]

Subpart C—Labeling Requirements for Over-the-Counter Devices

801.60 Principal display panel.

801.61 Statement of identity.

801.62 Declaration of net quantity of contents.

801.63 Medical devices; warning statements for devices containing or manufactured with chlorofluorocarbons and other class I ozone-depleting substances.

Subpart D—Exemptions From Adequate Directions for Use

801.109 Prescription devices.

801.110 Retail exemption for prescription devices.

801.116 Medical devices having commonly known directions.

801.119 In vitro diagnostic products.

801.122 Medical devices for processing, repackaging, or manufacturing.

801.125 Medical devices for use in teaching, law enforcement, research, and analysis.

801.126 Exemptions for cigarettes and smokeless tobacco.

801.127 Medical devices; expiration of exemptions.

Subpart E—Other Exemptions

801.150 Medical devices; processing, labeling, or repackaging.

Subparts F–G [Reserved]

Subpart H—Special Requirements for Specific Devices

- 801.405 Labeling of articles intended for lay use in the repairing and/or refitting of dentures.
- 801.410 Use of impact-resistant lenses in eyeglasses and sunglasses.
- 801.415 Maximum acceptable level of ozone.
- 800.417 Chlorofluorocarbon propellants.
- 801.420 Hearing aid devices; professional and patient labeling.
- 801.421 Hearing aid devices; conditions for sale.
- 801.430 User labeling for menstrual tampons.
- 801.433 Warning statements for prescription and restricted device products containing or manufactured with chlorofluorocarbons or other ozone-depleting substances.

AUTHORITY: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

SOURCE: 41 FR 6896, Feb. 13, 1976, unless otherwise noted.

Subpart A—General Labeling Provisions

§ 801.1 Medical devices; name and place of business of manufacturer, packer or distributor.

(a) The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for “Company,” “Incorporated,” etc., may be used and “The” may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(c) Where a device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such device; such as, “Manufactured for _____”, “Distributed by _____”, or

any other wording that expresses the facts.

(d) The statement of the place of business shall include the street address, city, State, and Zip Code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP Code shall appear on either the label or the labeling (including the invoice).

(e) If a person manufactures, packs, or distributes a device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such device was manufactured or packed or is to be distributed, unless such statement would be misleading.

§ 801.4 Meaning of “intended uses.”

The words “intended uses” or words of similar import in §§ 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses

other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

§801.5 Medical devices; adequate directions for use.

“Adequate directions for use” means directions under which the layman can use a device safely and for the purposes for which it is intended. Section 801.4 defines “intended use”. Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:

(a) Statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.

(c) Frequency of administration or application.

(d) Duration of administration or application.

(e) Time of administration or application, in relation to time of meals, time of onset of symptoms, or other time factors.

(f) Route or method of administration or application.

(g) Preparation for use, i.e., adjustment of temperature, or other manipulation or process.

§801.6 Medical devices; misleading statements.

Among representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device or a drug or food or cosmetic.

§801.15 Medical devices; prominence of required label statements.

(a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 502(c) of the act by reason, among other reasons, of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space for the prominent placing of such word, statement, or information, resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space for the placing of such word, statement, or information, resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 502(b) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word,

statement, or other information than is required by section 502(c) of the act; or

(3) The use of label space for any representation in a foreign language.

(c)(1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

§ 801.16 Medical devices; Spanish-language version of certain required statements.

If devices restricted to prescription use only are labeled solely in Spanish for distribution in the Commonwealth of Puerto Rico where Spanish is the predominant language, such labeling is authorized under § 801.15(c).

Subpart B [Reserved]

Subpart C—Labeling Requirements for Over-the-Counter Devices

§ 801.60 Principal display panel.

The term “principal display panel,” as it applies to over-the-counter devices in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and

without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term “area of the principal display panel” means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and

(c) In the case of any other shape of container, 40 percent of the total surface of the container: *Provided, however,* That where such container presents an obvious “principal display panel” such as the top of a triangular or circular package, the area shall consist of the entire top surface.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 801.61 Statement of identity.

(a) The principal display panel of an over-the-counter device in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of the common name of the device followed by an accurate statement of the principal intended action(s) of the device. Such statement shall be placed in direct conjunction with the most prominent display of the

name and shall employ terms descriptive of the principal intended action(s). The indications for use shall be included in the directions for use of the device, as required by section 502(f)(1) of the act and by the regulations in this part.

(c) The statement of identity shall be presented in bold face type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

§ 801.62 Declaration of net quantity of contents.

(a) The label of an over-the-counter device in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight, measure, or size: *Provided, That:*

(1) In the case of a firmly established general consumer usage and trade custom of declaring the quantity of a device in terms of linear measure or measure of area, such respective term may be used. Such term shall be augmented when necessary for accuracy of information by a statement of the weight, measure, or size of the individual units or of the entire device.

(2) If the declaration of contents for a device by numerical count does not give accurate information as to the quantity of the device in the package, it shall be augmented by such statement of weight, measure, or size of the individual units or of the total weight, measure, or size of the device as will give such information; for example, "100 tongue depressors, adult size", "1 rectal syringe, adult size", etc. Whenever the Commissioner determines for a specific packaged device that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination of these does not facilitate value comparisons by consumers, he shall by regulation designate the appropriate term or terms to be used for such article.

(b) Statements of weight of the contents shall be expressed in terms of avoirdupois pound and ounce. A state-

ment of liquid measure of the contents shall be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid-ounce subdivisions thereof, and shall express the volume at 68 °F (20 °C). See also paragraph (p) of this section.

(c) The declaration may contain common or decimal fractions. A common fraction shall be in terms of halves, quarters, eighths, sixteenths, or thirty-seconds; except that if there exists a firmly established, general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity, they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places. A statement that includes small fractions of an ounce shall be deemed to permit smaller variations than one which does not include such fractions.

(d) The declaration shall be located on the principal display panel of the label, and with respect to packages bearing alternate principal panels it shall be duplicated on each principal display panel.

(e) The declaration shall appear as a distinct item on the principal display panel, shall be separated, by at least a space equal to the height of the lettering used in the declaration, from other printed label information appearing above or below the declaration and, by at least a space equal to twice the width of the letter "N" of the style of type used in the quantity of contents statement, from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count, such as "giant pint" and "full quart", that tends to exaggerate. It shall be placed on the principal display panel within the bottom 30 percent of the area of the label panel in lines generally parallel to the base on which the package rests as it is designed to be displayed: *Provided, That:*

(1) On packages having a principal display panel of 5 square inches or less the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the

declaration of net quantity of contents meets the other requirements of this part; and

(2) In the case of a device that is marketed with both outer and inner retail containers bearing the mandatory label information required by this part and the inner container is not intended to be sold separately, the net quantity of contents placement requirement of this section applicable to such inner container is waived.

(3) The principal display panel of a device marketed on a display card to which the immediate container is affixed may be considered to be the display panel of the card, and the type size of the net quantity of contents statement is governed by the dimensions of the display card.

(f) The declaration shall accurately reveal the quantity of device in the package exclusive of wrappers and other material packed therewith.

(g) The declaration shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface. Requirements of conspicuousness and legibility shall include the specifications that:

(1) The ratio of height to width of the letter shall not exceed a differential of 3 units to 1 unit, i.e., no more than 3 times as high as it is wide.

(2) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter “o” or its equivalent that shall meet the minimum standards.

(3) When fractions are used, each component numeral shall meet one-half the minimum height standards.

(h) The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(1) Not less than one-sixteenth inch in height on packages the principal display

panel of which has an area of 5 square inches or less.

(2) Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches.

(3) Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(4) Not less than one-fourth inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than one-half inch in height if the area is more than 400 square inches.

Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in paragraphs (h)(1) through (4) of this section shall be increased by one-sixteenth of an inch.

(i) On packages containing less than 4 pounds or 1 gallon and labeled in terms of weight or fluid measure:

(1) The declaration shall be expressed both in ounces, with identification by weight or by liquid measure and, if applicable (1 pound or 1 pint or more) followed in parentheses by a declaration in pounds for weight units, with any remainder in terms of ounces or common or decimal fractions of the pound (see examples set forth in paragraphs (k) (1) and (2) of this section), or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see examples set forth in paragraphs (k) (3) and (4) of this section). If the net weight of the package is less than 1 ounce avoirdupois or the net fluid measure is less than 1 fluid ounce, the declaration shall be in terms of common or decimal fractions of the respective ounce and not in terms of drams.

(2) The declaration may appear in more than one line. The term “net weight” shall be used when stating the net quantity of contents in terms of weight. Use of the terms “net” or “net contents” in terms of fluid measure or

numerical count is optional. It is sufficient to distinguish avoirdupois ounce from fluid ounce through association of terms; for example, "Net wt. 6 oz" or "6 oz net wt.," and "6 fl oz" or "net contents 6 fl oz."

(j) On packages containing 4 pounds or 1 gallon or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds for weight units with any remainder in terms of ounces or common or decimal fractions of the pound; in the case of fluid measure, it shall be expressed in the largest whole unit, i.e., gallons, followed by common or decimal fractions of a gallon or by the next smaller whole unit or units (quarts or quarts and pints), with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart; see paragraph (k)(5) of this section.

(k) *Examples:* (1) A declaration of 1½ pounds weight shall be expressed as "net wt. 24 oz (1 lb 8 oz)," or "Net wt. 24 oz (1½ lb)" or "Net wt. 24 oz (1.5 lb)."

(2) A declaration of three-fourths pound avoirdupois weight shall be expressed as "Net wt. 12 oz."

(3) A declaration of 1 quart liquid measure shall be expressed as "Net contents 32 fl oz (1 qt)" or "32 fl oz (1 qt)."

(4) A declaration of 1¾ quarts liquid measure shall be expressed as, "Net contents 56 fl oz (1 qt 1 pt 8 oz)" or "Net contents 56 fl oz (1 qt 1.5 pt)," but not in terms of quart and ounce such as "Net contents 56 fl oz (1 qt 24 oz)."

(5) A declaration of 2½ gallons liquid measure shall be expressed as "Net contents 2 gal 2 qt", "Net contents 2.5 gallons," or "Net contents 2½ gal" but not as "2 gal 4 pt".

(l) For quantities, the following abbreviations and none other may be employed. Periods and plural forms are optional:

gallon gal	milliliter ml
quart qt	cubic centimeter cc
pint pt	yard yd
ounce oz	feet or foot ft
pound lb	inch in
grain gr	meter m
kilogram kg	centimeter cm
gram g	millimeter mm
milligram mg	fluid fl
microgram mcg	square sq
liter l	weight wt

(m) On packages labeled in terms of linear measure, the declaration shall be expressed both in terms of inches and, if applicable (1 foot or more), the largest whole units (yards, yards and feet, feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of inches and any remainder shall be in terms of inches or common or decimal fractions of the foot or yard; if applicable, as in the case of adhesive tape, the initial declaration in linear inches shall be preceded by a statement of the width. Examples of linear measure are "86 inches (2 yd 1 ft 2 in)", "90 inches (2½ yd)", "30 inches (2.5 ft)", "¾ inch by 36 in (1 yd)", etc.

(n) On packages labeled in terms of area measure, the declaration shall be expressed both in terms of square inches and, if applicable (1 square foot or more), the largest whole square unit (square yards, square yards and square feet, square feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of square inches and any remainder shall be in terms of square inches or common or decimal fractions of the square foot or square yard; for example, "158 sq inches (1 sq ft 14 sq in)".

(o) Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in nondeceptive terms the net quantity of contents, provided that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the device contained in the package; for example, "giant pint" and "full quart". Dual or combination declarations of net quantity of contents as provided for in paragraphs (a) and (i) of this section are not regarded as supplemental net quantity statements and shall be located on the principal display panel.

(p) A separate statement of net quantity of contents in terms of the metric system of weight or measure is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure

may also appear on the principal display panel or on other panels.

(q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

§ 801.63 Medical devices; warning statements for devices containing or manufactured with chlorofluorocarbons and other class I ozone-depleting substances.

(a) All over-the-counter devices containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other class I substance designated by the Environmental Protection Agency (EPA) shall carry one of the following warnings:

(1) The EPA warning statement:

WARNING: Contains [or Manufactured with, if applicable] *[insert name of substance]*, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

(2) The alternative statement:

NOTE: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or other class I substance, if applicable]:

WARNING: Contains [or Manufactured with, if applicable] *[insert name of substance]*, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

CONSULT WITH YOUR PHYSICIAN, HEALTH PROFESSIONAL, OR SUPPLIER IF YOU HAVE ANY QUESTION ABOUT THE USE OF THIS PRODUCT.

(b) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase. This provision does not replace or relieve a person from

any requirements imposed under 40 CFR part 82.

[61 FR 20101, May 3, 1996]

Subpart D—Exemptions From Adequate Directions for Use

§ 801.109 Prescription devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which “adequate directions for use” cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement “Caution: Federal law restricts this device to sale by or on the order of a _____”, the blank to be filled with the word “physician”, “dentist”, “veterinarian”, or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for

which it is advertised or represented: *Provided, however,* That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder—piece labeling which calls attention to the name of the device but does not include indications or other use information.

(e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

§801.110 Retail exemption for prescription devices.

A device subject to §801.109 shall be exempt at the time of delivery to the ultimate purchaser or user from section 502(f)(1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

§801.116 Medical devices having commonly known directions.

A device shall be exempt from section 502(f)(1) of the act insofar as adequate directions for common uses thereof are known to the ordinary individual.

§801.119 In vitro diagnostic products.

A product intended for use in the diagnosis of disease and which is an in vitro diagnostic product as defined in §809.3(a) of this chapter shall be deemed to be in compliance with the requirements of this section and section 502(f)(1) of the act if it meets the requirements of §809.10 of this chapter.

§801.122 Medical devices for processing, repacking, or manufacturing.

A device intended for processing, repacking, or use in the manufacture of another drug or device shall be exempt from section 502(f)(1) of the act if its label bears the statement "Caution: For manufacturing, processing, or repacking".

§801.125 Medical devices for use in teaching, law enforcement, research, and analysis.

A device subject to §801.109 shall be exempt from section 502(f)(1) of this act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing.

§801.126 Exemptions for cigarettes and smokeless tobacco.

Cigarettes and smokeless tobacco as defined in part 897 of this chapter are exempt from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act.

[61 FR 44615, Aug. 28, 1996]

EFFECTIVE DATE NOTE: At 61 FR 44615, Aug. 28, 1996, §801.126 was added, effective Aug. 28, 1997.

§ 801.127 Medical devices; expiration of exemptions.

(a) If a shipment or delivery, or any part thereof, of a device which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such shipment or delivery or part thereof, at the beginning of that shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such device being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device.

(b) The exemptions conferred by §§ 801.119, 801.122, and 801.125 shall continue until the devices are used for the purposes for which they are exempted, or until they are relabeled to comply with section 502(f)(1) of the act. If, however, the device is converted, or manufactured into a form limited to prescription dispensing, no exemption shall thereafter apply to the article unless the device is labeled as required by § 801.109.

Subpart E—Other Exemptions**§ 801.150 Medical devices; processing, labeling, or repacking.**

(a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked, in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of section 502(b) and (f) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such device is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of

such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such device in such establishment as will insure, if such specifications are followed, that such device will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such device from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(b) An exemption of a shipment or other delivery of a device under paragraph (a)(1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(c) An exemption of a shipment or other delivery of a device under paragraph (a)(2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such paragraph (a)(2).

(d) An exemption of a shipment or other delivery of a device under paragraph (a)(2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(2) Upon refusal by the operator of the establishment where such device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

(e) As it is a common industry practice to manufacture and/or assemble, package, and fully label a device as sterile at one establishment and then

ship such device in interstate commerce to another establishment or to a contract sterilizer for sterilization, the Food and Drug Administration will initiate no regulatory action against the device as misbranded or adulterated when the nonsterile device is labeled sterile, provided all the following conditions are met:

(1) There is in effect a written agreement which:

(i) Contains the names and post office addresses of the firms involved and is signed by the person authorizing such shipment and the operator or person in charge of the establishment receiving the devices for sterilization.

(ii) Provides instructions for maintaining proper records or otherwise accounting for the number of units in each shipment to insure that the number of units shipped is the same as the number received and sterilized.

(iii) Acknowledges that the device is nonsterile and is being shipped for further processing, and

(iv) States in detail the sterilization process, the gaseous mixture or other media, the equipment, and the testing method or quality controls to be used by the contract sterilizer to assure that the device will be brought into full compliance with the Federal Food, Drug, and Cosmetic Act.

(2) Each pallet, carton, or other designated unit is conspicuously marked to show its nonsterile nature when it is introduced into and is moving in interstate commerce, and while it is being held prior to sterilization. Following sterilization, and until such time as it is established that the device is sterile and can be released from quarantine, each pallet, carton, or other designated unit is conspicuously marked to show that it has not been released from quarantine, e.g., "sterilized—awaiting test results" or an equivalent designation.

Subparts F–G [Reserved]

Subpart H—Special Requirements for Specific Devices

§ 801.405 Labeling of articles intended for lay use in the repairing and/or refitting of dentures.

(a) The American Dental Association and leading dental authorities have advised the Food and Drug Administration of their concern regarding the safety of denture reliners, repair kits, pads, cushions, and other articles marketed and labeled for lay use in the repairing, refitting, or cushioning of ill-fitting, broken, or irritating dentures. It is the opinion of dental authorities and the Food and Drug Administration that to properly repair and properly refit dentures a person must have professional knowledge and specialized technical skill. Laymen cannot be expected to maintain the original vertical dimension of occlusion and the centric relation essential in the proper repairing or refitting of dentures. The continued wearing of improperly repaired or refitted dentures may cause acceleration of bone resorption, soft tissue hyperplasia, and other irreparable damage to the oral cavity. Such articles designed for lay use should be limited to emergency or temporary situations pending the services of a licensed dentist.

(b) The Food and Drug Administration therefore regards such articles as unsafe and misbranded under the Federal Food, Drug, and Cosmetic Act, unless the labeling:

(1)(i) Limits directions for use for denture repair kits to emergency repairing pending unavoidable delay in obtaining professional reconstruction of the denture;

(ii) Limits directions for use for denture reliners, pads, and cushions to temporary refitting pending unavoidable delay in obtaining professional reconstruction of the denture;

(2) Contains in a conspicuous manner the word "emergency" preceding and

modifying each indication-for-use statement for denture repair kits and the word “temporary” preceding and modifying each indication-for-use statement for reliners, pads, and cushions; and

(3) Includes a conspicuous warning statement to the effect:

(i) For denture repair kits: “*Warning—For emergency repairs only.* Long term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit for emergency use only. See Dentist Without Delay.”

(ii) For denture reliners, pads, and cushions: “*Warning—For temporary use only.* Longterm use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until a Dentist Can Be Seen.”

(c) Adequate directions for use require full information of the temporary and emergency use recommended in order for the layman to understand the limitations of usefulness, the reasons therefor, and the importance of adhering to the warnings. Accordingly, the labeling should contain substantially the following information:

(1) For denture repair kits: Special training and tools are needed to repair dentures to fit properly. Home-repaired dentures may cause irritation to the gums and discomfort and tiredness while eating. Long term use may lead to more troubles, even permanent changes in bones, teeth, and gums, which may make it impossible to wear dentures in the future. For these reasons, dentures repaired with this kit should be used only in an emergency until a dentist can be seen. Dentures that don't fit properly cause irritation and injury to the gums and faster bone loss, which is permanent. Dentures that don't fit properly cause gum changes that may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible.

(2) For denture reliners, pads, and cushions: Use of these preparations or devices may temporarily decrease the discomfort; however, their use will not make the denture fit properly. Special training and tools are needed to repair a denture to fit properly. Dentures that

do not fit properly cause irritation and injury to the gums and faster bone loss, which is permanent and may require a completely new denture. Changes in the gums caused by dentures that do not fit properly may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible.

(3) If the denture relining or repairing material forms a permanent bond with the denture, a warning statement to the following effect should be included: “This reliner becomes fixed to the denture and a completely new denture may be required because of its use.”

(d) Labeling claims exaggerating the usefulness or the safety of the material or failing to disclose all facts relevant to the claims of usefulness will be regarded as false and misleading under sections 201(n) and 502(a) of the Federal Food, Drug, and Cosmetic Act.

(e) Regulatory action may be initiated with respect to any article found within the jurisdiction of the act contrary to the provisions of this policy statement after 90 days following the date of publication of this section in the FEDERAL REGISTER.

§ 801.410 Use of impact-resistant lenses in eyeglasses and sunglasses.

(a) Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicates that the use of such lenses constitutes an avoidable hazard to the eye of the wearer.

(b) The consensus of the ophthalmic community is that the number of eye injuries would be substantially reduced by the use in eyeglasses and sunglasses of impact-resistant lenses.

(c)(1) To protect the public more adequately from potential eye injury, eyeglasses and sunglasses must be fitted with impact-resistant lenses, except in those cases where the physician or optometrist finds that such lenses will not fulfill the visual requirements of the particular patient, directs in writing the use of other lenses, and gives written notification thereof to the patient.

(2) The physician or optometrist shall have the option of ordering glass

lenses, plastic lenses, or laminated glass lenses made impact resistant by any method; however, all such lenses shall be capable of withstanding the impact test described in paragraph (d)(2) of this section.

(3) Each finished impact-resistant glass lens for prescription use shall be individually tested for impact resistance and shall be capable of withstanding the impact test described in paragraph (d)(2) of this section. Raised multifocal lenses shall be impact resistant but need not be tested beyond initial design testing. Prism segment multifocal, slab-off prism, lenticular cataract, iseikonic, depressed segment one-piece multifocal, bioconcave, myodisc and minus lenticular, custom laminate and cemented assembly lenses shall be impact resistant but need not be subjected to impact testing. To demonstrate that all other types of impact-resistant lenses, including impact-resistant laminated glass lenses (i.e., lenses other than those described in the three preceding sentences of this paragraph (c)(3)), are capable of withstanding the impact test described in this regulation, the manufacturer of these lenses shall subject to an impact test a statistically significant sampling of lenses from each production batch, and the lenses so tested shall be representative of the finished forms as worn by the wearer, including finished forms that are of minimal lens thickness and have been subjected to any treatment used to impart impact resistance. All non-prescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut-finished or finished form.

(d)(1) For the purpose of this regulation, the impact test described in paragraph (d)(2) of this section shall be the "referee test," defined as "one which will be utilized to determine compliance with a regulation." The referee test provides the Food and Drug Administration with the means of examining a medical device for performance and does not inhibit the manufacturer from using equal or superior test methods. A lens manufacturer shall conduct tests of lenses using the impact test described in paragraph (d)(2) of this section or any equal or superior test.

Whatever test is used, the lenses shall be capable of withstanding the impact test described in paragraph (d)(2) of this section if the Food and Drug Administration examines them for performance.

(2) In the impact test, a $\frac{5}{8}$ -inch steel ball weighing approximately 0.56 ounce is dropped from a height of 50 inches upon the horizontal upper surface of the lens. The ball shall strike within a $\frac{5}{8}$ -inch diameter circle located at the geometric center of the lens. The ball may be guided but not restricted in its fall by being dropped through a tube extending to within approximately 4 inches of the lens. To pass the test, the lens must not fracture; for the purpose of this section, a lens will be considered to have fractured if it cracks through its entire thickness, including a laminar layer, if any, and across a complete diameter into two or more separate pieces, or if any lens material visible to the naked eyes becomes detached from the ocular surface. The test shall be conducted with the lens supported by a tube (1-inch inside diameter, $1\frac{1}{4}$ -inch outside diameter, and approximately 1-inch high) affixed to a rigid iron or steel base plate. The total weight of the base plate and its rigidly attached fixtures shall be not less than 27 pounds. For lenses of small minimum diameter, a support tube having an outside diameter of less than $1\frac{1}{4}$ inches may be used. The support tube shall be made of rigid acrylic plastic, steel, or other suitable substance and shall have securely bonded on the top edge a $\frac{1}{8}$ - by $\frac{1}{8}$ -inch neoprene gasket having a hardness of 40 ± 5 , as determined by ASTM Method D 1415-68 "Test for International Hardness of Vulcanized Rubber," a minimum tensile strength of 1,200 pounds, as determined by ASTM Method D 412-68 "Tension Test of Vulcanized Rubber," and a minimum ultimate elongation of 400 percent, as determined by ASTM Method D 412-68 (Both methods are incorporated by reference and are available from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408). The diameter or contour of the lens support may be

modified as necessary so that the 1/8- by 1/8-inch neoprene gasket supports the lens at its periphery.

(e) Copies of invoice(s), shipping document(s), and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, shall be kept and maintained for a period of 3 years; however, the names and addresses of individuals purchasing nonprescription eyeglasses and sunglasses at the retail level need not be kept and maintained by the retailer. The records kept in compliance with this paragraph shall be made available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration or by any other officer or employee acting on behalf of the Secretary of Health and Human Services and such officer or employee shall be permitted to inspect and copy such records, to make such inventories of stock as he deems necessary, and otherwise to check the correctness of such inventories.

(f) In addition, those persons conducting tests in accordance with paragraph (d) of this section shall maintain the results thereof and a description of the test method and of the test apparatus for a period of 3 years. These records shall be made available upon request at any reasonable hour by any officer or employee acting on behalf of the Secretary of Health and Human Services. The persons conducting tests shall permit the officer or employee to inspect and copy the records, to make such inventories of stock as the officer or employee deems necessary, and otherwise to check the correctness of the inventories.

(g) For the purpose of this section, the term “manufacturer” includes an importer for resale. Such importer may have the tests required by paragraph (d) of this section conducted in the country of origin but must make the results thereof available, upon request, to the Food and Drug Administration, as soon as practicable.

(h) All lenses must be impact-resistant except when the physician or optometrist finds that impact-resistant lenses will not fulfill the visual requirements for a particular patient.

(i) This statement of policy does not apply to contact lenses.

[41 FR 6896, Feb. 13, 1976, as amended at 44 FR 20678, Apr. 6, 1979; 47 FR 9397, Mar. 5, 1982]

§ 801.415 Maximum acceptable level of ozone.

(a) Ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy. In order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals.

(b) Although undesirable physiological effects on the central nervous system, heart, and vision have been reported, the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema. The onset of pulmonary edema is usually delayed for some hours after exposure; thus, symptomatic response is not a reliable warning of exposure to toxic concentrations of ozone. Since olfactory fatigue develops readily, the odor of ozone is not a reliable index of atmospheric ozone concentration.

(c) A number of devices currently on the market generate ozone by design or as a byproduct. Since exposure to ozone above a certain concentration can be injurious to health, any such device will be considered adulterated and/or misbranded within the meaning of sections 501 and 502 of the act if it is used or intended for use under the following conditions:

(1) In such a manner that it generates ozone at a level in excess of 0.05 part per million by volume of air circulating through the device or causes an accumulation of ozone in excess of 0.05 part per million by volume of air (when measured under standard conditions at 25 °C (77 °F) and 760 millimeters of mercury) in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices. This applies to any such device, whether portable or permanent or part of any system, which generates ozone by design or as an inadvertent or incidental product.

(2) To generate ozone and release it into the atmosphere in hospitals or other establishments occupied by the ill or infirm.

(3) To generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed 0.05 part per million by volume of air circulating through the device) as established herein and the smallest area in which such device can be used so as not to produce an ozone accumulation in excess of 0.05 part per million.

(4) In any medical condition for which there is no proof of safety and effectiveness.

(5) To generate ozone at a level less than 0.05 part per million by volume of air circulating through the device and it is labeled for use as a germicide or deodorizer.

(d) This section does not affect the present threshold limit value of 0.10 part per million (0.2 milligram per cubic meter) of ozone exposure for an 8-hour-day exposure of industrial workers as recommended by the American Conference of Governmental Industrial Hygienists.

(e) The method and apparatus specified in 40 CFR part 50, or any other equally sensitive and accurate method, may be employed in measuring ozone pursuant to this section.

§ 801.417 Chlorofluorocarbon propellants.

The use of chlorofluorocarbon in devices as propellants in self-pressurized containers is generally prohibited except as provided in § 2.125 of this chapter.

[43 FR 11318, Mar. 17, 1978]

§ 801.420 Hearing aid devices; professional and patient labeling.

(a) *Definitions for the purposes of this section and § 801.421.* (1) "Hearing aid" means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

(2) "Ear specialist" means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of

deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

(3) "Dispenser" means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association.

(4) "Audiologist" means any person qualified by training and experience to specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

(5) "Sale" or "purchase" includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

(6) "Used hearing aid" means any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered "used" merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

(b) *Label requirements for hearing aids.* Hearing aids shall be clearly and permanently marked with:

(1) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture.

(2) A "+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

(c) *Labeling requirements for hearing aids—(1) General.* All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be developed by

the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with § 801.421(c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

(i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.

(ii) Information on the function of all controls intended for user adjustment.

(iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.

(iv) Specific instructions for:

(a) Use of the hearing aid.

(b) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(c) Replacing or recharging the batteries, including a generic designation of replacement batteries.

(v) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.

(vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, or exposing the hearing aid to excessive heat.

(vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

(ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

(x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

(xi) The warning statement required by paragraph (c)(2) of this section.

(xii) The notice for prospective hearing aid users required by paragraph (c)(3) of this section.

(xiii) The technical data required by paragraph (c)(4) of this section, unless such data is provided in separate labeling accompanying the device.

(2) *Warning statement.* The User Instructional Brochure shall contain the following warning statement:

WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

(i) Visible congenital or traumatic deformity of the ear.

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

(v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

(vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(3) *Notice for prospective hearing aid users.* The User Instructional Brochure shall contain the following notice:

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a

physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

(4) *Technical data.* Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test

procedures of the American National Standard "Specification of Hearing Aid Characteristics," ANSI S3.22-1987 (ASA 70-1987) (Revision of S3.22-1982), which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or are available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408. As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

- (i) Saturation output curve (SSPL 90 curve).
- (ii) Frequency response curve.
- (iii) Average saturation output (HF-Average SSPL 90).
- (iv) Average full-on gain (HF-Average full-on gain).
- (v) Reference test gain.
- (vi) Frequency range.
- (vii) Total harmonic distortion.
- (viii) Equivalent input noise.
- (ix) Battery current drain.
- (x) Induction coil sensitivity (telephone coil aids only).
- (xi) Input-output curve (ACG aids only).
- (xii) Attack and release times (ACG aids only).

(5) *Statement if hearing aid is used or rebuilt.* If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(6) *Statements in User Instructional Brochure other than those required.* A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

- (i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and
- (ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission.

(d) *Submission of all labeling for each type of hearing aid.* Any manufacturer of a hearing aid described in paragraph (a) of this section shall submit to the

Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Division of Compliance, HFK-116, 8757 Georgia Ave., Silver Spring, MD 20910, a copy of the User Instructional Brochure described in paragraph (c) of this section and all other labeling for each type of hearing aid on or before August 15, 1977.

[42 FR 9294, Feb. 15, 1977, as amended at 47 FR 9398, Mar. 5, 1982; 50 FR 30154, July 24, 1985; 54 FR 52396, Dec. 21, 1989]

§801.421 Hearing aid devices; conditions for sale.

(a) *Medical evaluation requirements—*

(1) *General.* Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.

(2) *Waiver to the medical evaluation requirements.* If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a)(1) of this section provided that the hearing aid dispenser:

(i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;

(ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and

(iii) Affords the prospective user the opportunity to sign the following statement:

I have been advised by _____ (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

(b) *Opportunity to review User Instructional Brochure.* Before signing any statement under paragraph (a)(2)(iii) of

this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

(1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;

(2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale;

(3) Afford the prospective user an opportunity to read the User Instructional Brochure.

(c) *Availability of User Instructional Brochure.* (1) Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

(2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes:

(i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users;

(ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

(d) *Recordkeeping.* The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a)(1) of this section or any written statement waiving medical evaluation required under paragraph (a)(2)(iii) of this section.

(e) *Exemption for group auditory trainers.* Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.

[42 FR 9296, Feb. 15, 1977]

§ 801.430 User labeling for menstrual tampons.

(a) This section applies to scented or scented deodorized menstrual tampons as identified in § 884.5460 and unscented menstrual tampons as identified in § 884.5470 of this chapter.

(b) Data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c), (d), and (e) of this section and tested for absorbency as set forth in paragraph (f) of this section.

(c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement shall appear prominently and legibly on the package label:

ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.

(d) The labeling of menstrual tampons shall contain the following consumer information prominently and legibly, in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use:

(i) Warning signs of TSS, e.g., sudden fever (usually 102° or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;

(ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated incidence of TSS of 1 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS;

(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

(5) The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

(e) The statements required by paragraph (e) of this section shall be prominently and legibly placed on the package label of menstrual tampons in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (unless the menstrual tampons are exempt under paragraph (g) of this section).

(1) Menstrual tampon package labels shall bear one of the following absorbency terms representing the absorbency of the production run, lot, or batch as measured by the test described in paragraph (f)(2) of this section;

Ranges of absorbency in grams ¹	Corresponding term of absorbency
6 and under	Junior absorbency.
6 to 9	Regular absorbency.
9 to 12	Super absorbency.
12 to 15	Super plus absorbency.
15 to 18	None.
above 18	None.

¹ These ranges are defined, respectively, as follows: less than or equal to 6 grams; greater than 6 grams up to and including 9 grams; greater than 9 grams up to and including 12 grams; greater than 12 grams up to and including 15 grams; greater than 15 grams up to and including 18 grams; and greater than 18 grams.

(2) The package label shall include an explanation of the ranges of absorbency and a description of how consumers can use a range of absorbency, and its corresponding absorbency term, to make comparisons of absorbency of tampons to allow selection of the tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS.

(f) A manufacturer shall measure the absorbency of individual tampons using the test method specified in paragraph (f)(2) of this section and calculate the mean absorbency of a production run, lot, or batch by rounding to the nearest 0.1 gram.

(1) A manufacturer shall design and implement a sampling plan that includes collection of probability samples of adequate size to yield consistent tolerance intervals such that the probability is 90 percent that at least 90 percent of the absorbencies of individual tampons within a brand and type are within the range of absorbency stated on the package label.

(2) In the absorbency test, an unlubricated condom, with tensile strength between 17 Mega Pascals (MPa) and 30 MPa, as measured according to the procedure in the American Society for Testing and Materials (ASTM), D 3492-83, "Standard Specification for Rubber Contraceptives (Condoms)"¹ for determining tensile strength, which is incorporated by reference in accordance with 5 U.S.C. 552(a), is attached to the large end of a glass chamber (or a chamber made from hard transparent plastic) with a rubber band (see Figure 1) and pushed through the small end of the chamber using a smooth, finished rod. The condom is pulled through until all slack is removed. The tip of the condom is cut off and the remaining

end of the condom is stretched over the end of the tube and secured with a rubber band. A preweighed (to the nearest 0.01 gram) tampon is placed within the condom membrane so that the center of gravity of the tampon is at the center of the chamber. An infusion needle (14 gauge) is inserted through the septum created by the condom tip until it contacts the end of the tampon. The outer chamber is filled with water pumped from a temperature-controlled waterbath to maintain the average temperature at $27\pm 1^{\circ}$ C. The water returns to the waterbath as shown in Figure 2. Syngyna fluid (10 grams sodium chloride, 0.5 gram Certified Reagent Acid Fushsin, 1,000 milliliters distilled water) is then pumped through the infusion needle at a rate of 50 milliliters per hour. The test shall be terminated when the tampon is saturated and the first drop of fluid exits the apparatus. (The test result shall be discarded if fluid is detected in the folds of the condom before the tampon is saturated). The water is then drained and the tampon is removed and immediately weighed to the nearest 0.01 gram. The absorbency of the tampon is determined by subtracting its dry weight from this value. The condom shall be replaced after 10 tests or at the end of the day during which the condom is used in testing, whichever occurs first.

¹Copies of the standard are available from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

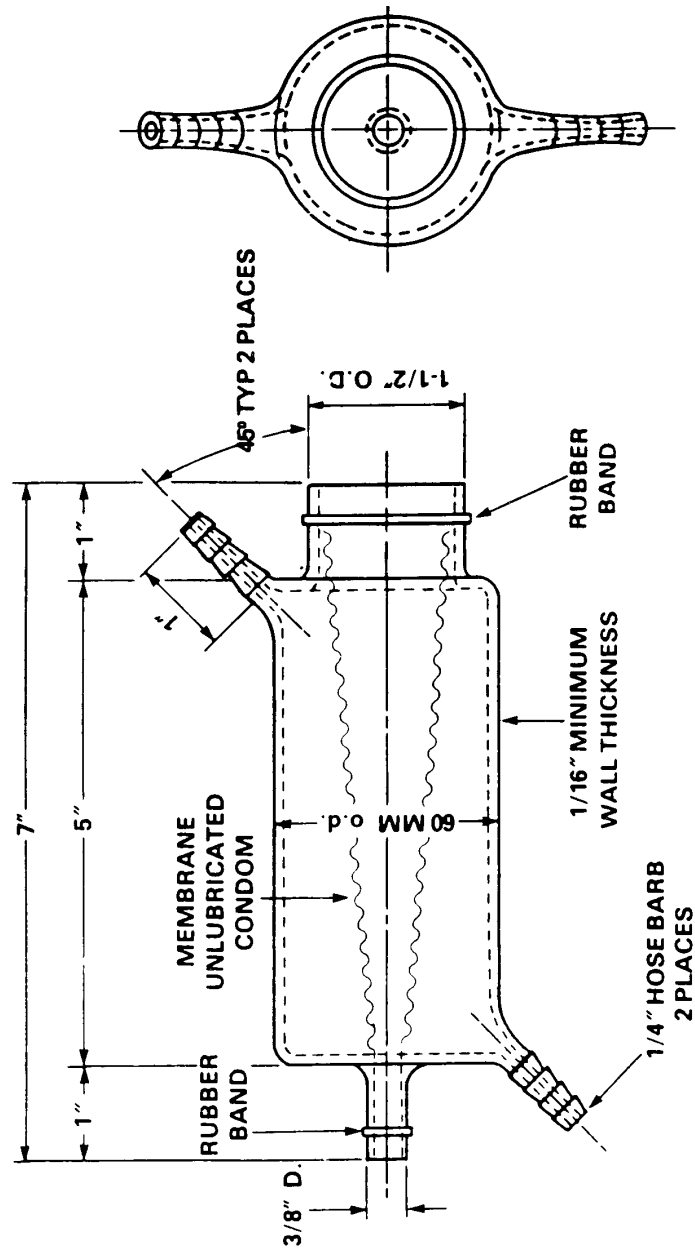


FIGURE 1 — SYNGYNA TEST CHAMBER

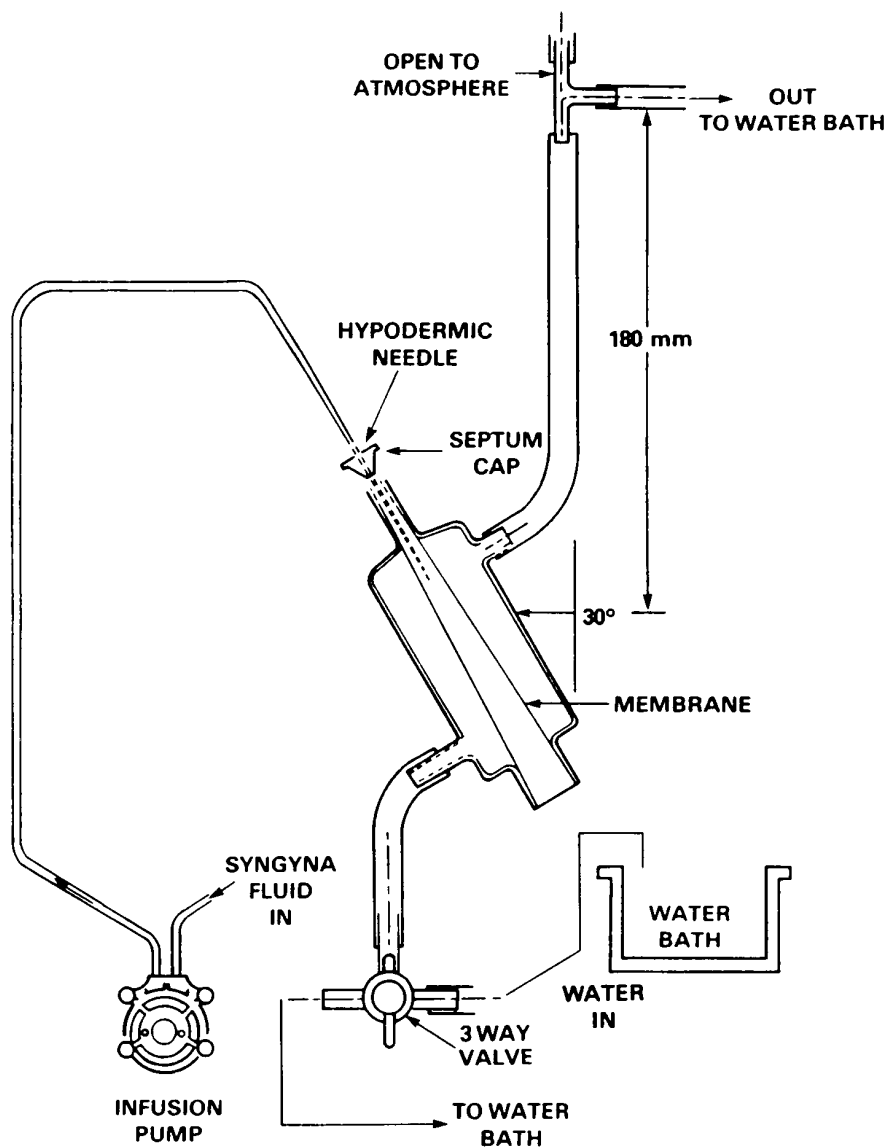


FIGURE 2—SYNGYNA TEST SET-UP

(3) The Food and Drug Administration may permit the use of an absorbency test method different from the

test method specified in this section if each of the following conditions is met:

(i) The manufacturer presents evidence, in the form of a citizen petition

submitted in accordance with the requirements of §10.30 of this chapter, demonstrating that the alternative test method will yield results that are equivalent to the results yielded by the test method specified in this section; and

(ii) FDA approves the method and has published notice of its approval of the alternative test method in the FEDERAL REGISTER.

(g) Any menstrual tampon intended to be dispensed by a vending machine is exempt from the requirements of this section.

(h) Any menstrual tampon that is not labeled as required by paragraphs (c), (d), and (e) of this section and that is initially introduced or initially delivered for introduction into commerce after March 1, 1990, is misbranded under sections 201(n), 502 (a) and (f) of the act.

(Information collection requirements contained in paragraphs (e) and (f) were approved by the Office of Management and Budget under control number 0910-0257)

[47 FR 26989, June 22, 1982, as amended at 54 FR 43771, Oct. 26, 1989; 55 FR 17600, Apr. 26, 1990]

§ 801.433 Warning statements for prescription and restricted device products containing or manufactured with chlorofluorocarbons or other ozone-depleting substances.

(a)(1) All prescription and restricted device products containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other class I substance designated by the Environmental Protection Agency (EPA) shall, except as provided in paragraph (b) of this section, bear the following warning statement:

WARNING: Contains [or Manufactured with, if applicable] *[insert name of substance]*, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

(2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and under-

stood by consumers under normal conditions of purchase.

(b)(1) For prescription and restricted device products, the following alternative warning statement may be used:

NOTE: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or name of other class I substance, if applicable]:

This product contains [or is manufactured with, if applicable] *[insert name of substance]*, a substance which harms the environment by destroying ozone in the upper atmosphere.

Your physician has determined that this product is likely to help your personal health. USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY YOUR PHYSICIAN. If you have any questions about alternatives, consult with your physician.

(2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase.

(3) If the warning statement in paragraph (b)(1) of this section is used, the following warning statement must be placed on the package labeling intended to be read by the physician (physician package insert) after the "How supplied" section, which describes special handling and storage conditions on the physician labeling:

NOTE: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or name of other class I substance, if applicable]:

WARNING: Contains [or Manufactured with, if applicable] *[insert name of substance]*, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

A notice similar to the above WARNING has been placed in the information for the patient [or patient information leaflet, if applicable] of this product under Environmental Protection Agency (EPA) regulations. The patient's warning states that the patient should consult his or her physician if there are questions about alternatives.

(c) This section does not replace or relieve a person from any requirements imposed under 40 CFR part 82.

[61 FR 20101, May 3, 1996]

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec.

803.1 Scope.

803.3 Definitions.

803.9 Public availability of reports.

803.10 General description of reports required from user facilities and manufacturers.

803.11 Obtaining the forms.

803.12 Where to submit reports.

803.13 English reporting requirement.

803.14 Electronic reporting.

803.15 Requests for additional information.

803.16 Disclaimers.

803.17 Written MDR procedures.

803.18 Files.

803.19 Exemptions, variances, and alternative reporting requirements.

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

803.20 How to report.

803.21 Reporting codes.

803.22 When not to file.

Subpart C—User Facility Reporting Requirements

803.30 Individual adverse event reports; user facilities.

803.32 Individual adverse event report data elements.

803.33 Semiannual reports.

Subpart D [Reserved]

Subpart E—Manufacturer Reporting Requirements

803.50 Individual adverse event reports; manufacturers.

803.52 Individual adverse event report data elements.

803.53 Five-day reports.

803.55 Baseline reports.

803.56 Supplemental reports.

803.57 Annual certification.

803.58 Foreign manufacturers.

AUTHORITY: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

SOURCE: 60 FR 63597, Dec. 11, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 803.1 Scope.

(a) This part establishes requirements for medical device reporting. Under this part, medical device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed, and manufacturers must also report certain device malfunctions. Additionally, user facilities and manufacturers must establish and maintain adverse event files, and must submit to FDA specified followup and summary reports. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(b) This part supplements and does not supersede other provisions of this subchapter, including the provisions of part 820 of this chapter.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of title 21, unless otherwise noted.

[60 FR 63597, Dec. 11, 1995, as amended at 62 FR 13306, Mar. 20, 1996]

EFFECTIVE DATE NOTE: At 62 FR 13306, Mar. 20, 1997, in § 803.1, paragraph (a) was revised, effective May 19, 1997. For the convenience of the user, the superseded text is set forth as follows:

§ 803.1 Scope.

(a) This part establishes requirements for medical device reporting. Under this part, device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed, and must establish and maintain adverse event files. Manufacturers are also required to report certain device malfunctions and submit an annual report to FDA certifying that the correct number of medical device reports were filed during the previous 12-month period or, alternatively, that no reports were required during that same time period. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

* * * * *

§ 803.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Ambulatory surgical facility (ASF)* means a distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.

(c) *Become aware* means that an employee of the entity required to report has acquired information reasonably suggesting a reportable adverse event has occurred. Device user facilities are considered to have “become aware” when medical personnel, as defined in paragraph (r) of this section, who are employed by or otherwise formally affiliated with the facility, acquire such information about a reportable event. Manufacturers are considered to have “become aware” of an event when:

(1) Any employee becomes aware of a reportable event that is required to be reported within 30 days, or that is required to be reported within 5 days pursuant to a written request from FDA under 803.53(b); and

(2) Any employee, who is a person with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, becomes aware that a reportable MDR event or events, from any information, including any trend analysis, necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health.

(d) *Caused or contributed* means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

(1) Failure;

(2) Malfunction;

(3) Improper or inadequate design;

(4) Manufacture;

(5) Labeling; or

(6) User error.

(e)(1) *Device family* means a group of one or more devices manufactured by or for the same manufacturer and having the same:

(i) Basic design and performance characteristics related to device safety and effectiveness,

(ii) Intended use and function, and

(iii) Device classification and product code.

(2) Devices that differ only in minor ways not related to safety or effectiveness can be considered to be in the same device family. Factors such as brand name and common name of the device and whether the devices were introduced into commercial distribution under the same 510(k) or premarket approval application (PMA), may be considered in grouping products into device families.

(f) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in paragraphs (l), (b), (s), (t), and (u), respectively, of this section, which is not a “physician’s office,” as defined in paragraph (w) of this section. School nurse offices and employee health units are not device user facilities.

(g)-(h) [Reserved]

(i) *Expected life* of a device (required on the manufacturer’s baseline report) means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified “end of life” (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through maintenance, repair, upgrades, etc., for an estimated period of time.

(j) *FDA* means the Food and Drug Administration.

(k) *Five-day report* means a medical device report that must be submitted by a manufacturer to FDA pursuant to § 803.53, on FDA Form 3500A or electronic equivalent as approved under § 803.14, within 5 work days.

(l) *Hospital* means a distinct entity that operates for the primary purpose

of providing diagnostic, therapeutic (medical, occupational, speech, physical, etc.), surgical and other patient services for specific and general medical conditions. Hospitals include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (e.g., not a part of a provider of services or any other facility) or may be operated by another medical entity (e.g., under the common ownership, licensure or control of another entity). A hospital is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the hospital must report that event regardless of the nature or location of the medical service provided by the hospital.

(m) *Malfunction* means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in §801.4 of this chapter.

(n) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or

(4) Is the U.S. agent of a foreign manufacturer.

(o) *Manufacturer report number* means the number that uniquely identifies each individual adverse event report submitted by a manufacturer. This number consists of three parts as follows:

(1) The FDA registration number for the manufacturing site of the reported device. (If the manufacturing site does not have a registration number, FDA will assign a temporary number until the site is officially registered. The manufacturer will be informed of the temporary number.);

(2) The four-digit calendar year in which the report is submitted; and

(3) The five-digit sequence number of the reports submitted during the year, starting with 00001. (For example, the complete number will appear 1234567-1995-00001.)

(p) *MDR* means medical device report.

(q) *MDR reportable event* (or *reportable event*) means:

(1) An event about which user facilities become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or

(2) An event about which manufacturers have received or become aware of information that reasonably suggests that one of their marketed devices:

(i) May have caused or contributed to a death or serious injury; or

(ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(r) *Medical personnel*, as used in this part, means an individual who:

(1) Is licensed, registered, or certified by a State, territory, or other governing body, to administer health care;

(2) Has received a diploma or a degree in a professional or scientific discipline;

(3) Is an employee responsible for receiving medical complaints or adverse event reports; or

(4) Is a supervisor of such persons.

(s)(1) *Nursing home* means an independent entity (i.e., not a part of a provider of services or any other facility) or one operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:

(i) Skilled nursing care and related services for persons who require medical or nursing care;

(ii) Hospice care to the terminally ill; or

(iii) Services for the rehabilitation of the injured, disabled, or sick.

(2) A nursing home is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature, or location of the medical service provided by the nursing home.

(t)(1) *Outpatient diagnostic facility* means a distinct entity that:

(i) Operates for the primary purpose of conducting medical diagnostic tests on patients;

(ii) Does not assume ongoing responsibility for patient care; and

(iii) Provides its services for use by other medical personnel. (Examples include diagnostic radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography and in-vitro testing).

(2) An outpatient diagnostic facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.

(u)(1) *Outpatient treatment facility* means a distinct entity that operates for the primary purpose of providing nonsurgical therapeutic (medical, occupational, or physical) care on an outpatient basis or home health care setting. Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse.

(2) An outpatient treatment facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.

(v) *Patient of the facility* means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. For the purposes of this part, the definition encompasses employees of the facility or individuals affiliated with the facility, who in the course of their duties suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.

(w) *Physician's office* means a facility that operates as the office of a physician or other health care professional (e.g., dentist, chiropractor, optometrist, nurse practitioner, school nurse offices, school clinics, employee health clinics, or free-standing care units) for the primary purpose of examination, evaluation, and treatment or referral of patients. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.

(x) [Reserved]

(y) *Remedial action* means, for the purposes of this subpart, any action other than routine maintenance or servicing, of a device where such action is necessary to prevent recurrence of a reportable event.

(z) [Reserved]

(aa)(1) *Serious injury* means an injury or illness that:

- (i) Is life-threatening;
- (ii) Results in permanent impairment of a body function or permanent damage to body structure; or
- (iii) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(2) *Permanent* means, for purposes of this subpart, irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

(bb) *Shelf life*, as required on the manufacturer's baseline report, means the maximum time a device will remain functional from the date of manufacture until it is used in patient care. Some devices have an expiration date on their labeling indicating the maximum time they can be stored before losing their ability to perform their intended function.

(cc) [Reserved]

(dd)(1) *User facility report number* means the number that uniquely identifies each report submitted by a user facility to manufacturers and FDA. This number consists of three parts as follows:

- (i) The user facility's 10-digit Health Care Financing Administration (HCFA) number (if the HCFA number has fewer than 10 digits, fill the remaining spaces with zeros);
- (ii) The four-digit calendar year in which the report is submitted; and
- (iii) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete number will appear as follows: 1234560000–1995–0001.)

(2) If a facility has more than one HCFA number, it must select one that will be used for all of its MDR reports. If a facility has no HCFA number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000–1995–0001) and FDA will assign a number for future use. The num-

ber assigned will be used in FDA's record of that report and in any correspondence with the user facility. All zeros should be used subsequent to the first report if the user does not receive FDA's assigned number before the next report is submitted. If a facility has multiple sites, the primary site can report centrally and use one reporting number for all sites if the primary site provides the name, address and HCFA number for each respective site.

(ee) *Work day* means Monday through Friday, excluding Federal holidays.

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, in § 803.3, paragraph (n)(4) was stayed indefinitely.

§ 803.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter;

(2) Any personal, medical, and similar information (including the serial number of implanted devices), which would constitute an invasion of personal privacy under § 20.63 of this chapter. FDA will disclose to a patient who requests a report, all the information in the report concerning that patient, as provided in § 20.61 of this chapter; and

(3) Any names and other identifying information of a third party voluntarily submitting an adverse event report.

(c) FDA may not disclose the identity of a device user facility which makes a report under this part except in connection with:

(1) An action brought to enforce section 301(q) of the act, including the failure or refusal to furnish material or information required by section 519 of the act;

(2) A communication to a manufacturer of a device which is the subject of a report required by a user facility under § 803.30;

(3) A disclosure relating to a manufacturer or distributor adverse event

report that is required under section 519(a) of the act; or

(4) A disclosure to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

§ 803.10 General description of reports required from user facilities and manufacturers.

(a) *Device user facilities.* User facilities must submit the following reports, which are described more fully in subpart C of this part.

(1) User facilities must submit MDR reports of individual adverse events within 10 days after the user facility becomes aware of an MDR reportable event as described in §§ 803.30 and 803.32.

(i) User facilities must submit reports of device-related deaths to FDA and to the manufacturer, if known.

(ii) User facilities must submit reports of device-related serious injuries to manufacturers, or to FDA, if the manufacturer is unknown.

(2) User facilities must submit semi-annual reports as described in § 803.33.

(b) [Reserved]

(c) *Device manufacturers.* Manufacturers must submit the following reports as described more fully in subpart E of this part:

(1) MDR reports of individual adverse events within 30 days after the manufacturer becomes aware of a reportable death, serious injury, or malfunction as described in §§ 803.50 and 803.52.

(2) MDR reports of individual adverse events within 5 days of:

(i) Becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health or,

(ii) Becoming aware of an MDR reportable event for which FDA has made a written request, as described in § 803.53.

(3) Annual baseline reports as described in § 803.55.

(4) Supplemental reports if they obtain information that was not provided in an initial report as described in § 803.56.

(5) Annual certification to FDA of the number of MDR reports filed during the preceding year as described in § 803.57.

§ 803.11 Obtaining the forms.

User facilities and manufacturers must submit all reports of individual adverse events on FDA Form 3500A (MEDWATCH form) or in an electronic equivalent as approved under § 803.14. This form and all other forms referenced in this section can also be obtained from the Consolidated Forms and Publications Office, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785, or from the Division of Small Manufacturers Assistance, Office of Health and Industry Programs, Center for Devices and Radiological Health, 1350 Piccard Dr. (HFZ-220), Rockville, MD 20850, telephone facsimile (FAX) 301-443-8818. FDA Form 3500A may also be obtained from the Food and Drug Administration, MEDWATCH (HF-2), 5600 Fishers Lane, rm. 9-57, Rockville, MD 20850, 301-443-0117.

§ 803.12 Where to submit reports.

(a) Any written report or additional information required under this part shall be submitted to: Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, PO Box 3002, Rockville, MD 20847-3002.

(b) Each report and its envelope shall be specifically identified, e.g., "User Facility Report," "SemiAnnual Report," "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

(c) If an entity is confronted with a public health emergency, this can be brought to FDA's attention by contacting the FDA Emergency Operations Branch (HFC-162), Office of Regional Operations, at 301-443-1240, and should be followed by the submission of a FAX report to 301-443-3757.

(d) A voluntary telephone report may be submitted to, or information regarding voluntary reporting may be obtained from, the MEDWATCH hotline at 800-FDA-1088.

§ 803.13 English reporting requirement.

(a) All reports required in this part which are submitted in writing or electronic equivalent shall be submitted to FDA in English.

(b) All reports required in this part which are submitted on an electronic

medium shall be submitted to FDA in a manner consistent with § 803.14.

§ 803.14 Electronic reporting.

(a) Any report required by this part may be submitted electronically with prior written consent from FDA. Such consent is revocable. Electronic report submissions include alternative reporting media (magnetic tape, disc, etc.) and computer-to-computer communication.

(b) Any electronic report meeting electronic reporting standards, guidelines, or other procedures developed by the agency for MDR reporting will be deemed to have prior approval for use.

§ 803.15 Requests for additional information.

(a) FDA may determine that protection of the public health requires additional or clarifying information for medical device reports submitted to FDA under this part. In these instances, and in cases when the additional information is beyond the scope of FDA reporting forms or is not readily accessible, the agency will notify the reporting entity in writing of the additional information that is required.

(b) Any request under this section shall state the reason or purpose for which the information is being requested, specify the date that the information is to be submitted and clearly relate the request to a reported event. All verbal requests will be confirmed in writing by the agency.

§ 803.16 Disclaimers.

A report or other information submitted by a reporting entity under this part, and any release by FDA of that report or information, does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, or the reporting entity or its employees, caused or contributed to the reportable event. The reporting entity need not admit and may deny that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a reportable event.

§ 803.17 Written MDR procedures.

User facilities and manufacturers shall develop, maintain, and implement written MDR procedures for the following:

(a) Internal systems that provide for:

(1) Timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements;

(2) A standardized review process/procedure for determining when an event meets the criteria for reporting under this part; and

(3) Timely transmission of complete medical device reports to FDA and/or manufacturers;

(b) Documentation and record-keeping requirements for:

(1) Information that was evaluated to determine if an event was reportable;

(2) All medical device reports and information submitted to FDA and manufacturers;

(3) Any information that was evaluated for the purpose of preparing the submission of semiannual reports or certification; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by FDA.

§ 803.18 Files.

(a) User facilities and manufacturers shall establish and maintain MDR event files. All MDR event files shall be prominently identified as such and filed to facilitate timely access.

(b)(1) For purposes of this part, “MDR event files” are written or electronic files maintained by user facilities and manufacturers. MDR event files may incorporate references to other information, e.g., medical records, patient files, engineering reports, etc., in lieu of copying and maintaining duplicates in this file. MDR event files must contain:

(i) Information in the possession of the reporting entity or references to information related to the adverse event, including all documentation of the entity’s deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part.

(ii) Copies of all MDR forms, as required by this part, and other information related to the event that was submitted to FDA and other entities (e.g., a distributor or manufacturer).

(2) User facilities and manufacturers shall permit any authorized FDA employee during all reasonable times to access, to copy, and to verify the records required by this part.

(c) User facilities shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. Manufacturers shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. MDR event files must be maintained for the time periods described in this paragraph even if the device is no longer distributed.

(d) [Reserved]

(e) The manufacturer may maintain MDR event files as part of its complaint file, under §820.198 of this chapter, provided that such records are prominently identified as MDR reportable events. A report submitted under this subpart A shall not be considered to comply with this part unless the event has been evaluated in accordance with the requirements of §§820.162 and 820.198 of this chapter. MDR files shall contain an explanation of why any information required by this part was not submitted or could not be obtained. The results of the evaluation of each event are to be documented and maintained in the manufacturer's MDR event file.

§803.19 Exemptions, variances, and alternative reporting requirements.

(a) The following persons are exempt from the reporting requirements under this part.

(1) An individual who is a licensed practitioner who prescribes or administers devices intended for use in humans and who manufactures or imports devices solely for use in diagnosing and treating persons with whom the practitioner has a "physician-patient" relationship.

(2) An individual who manufactures devices intended for use in humans solely for such person's use in research

or teaching and not for sale, including any person who is subject to alternative reporting requirements under the investigational device exemption regulations, parts 812 and 813 of this chapter, which require reporting of all adverse device effects.

(3) Dental laboratories, or optical laboratories.

(b) Manufacturers or user facilities may request exemptions or variances from any or all of the reporting requirements in this part. The request shall be in writing and include information necessary to identify the firm and device, a complete statement of the request for exemption, variance, or alternative reporting, and an explanation why the request is justified.

(c) FDA may grant in writing, to a manufacturer or user facility, an exemption, variance or alternative from, or to, any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time period. These modifications may be initiated by a request as specified in this section, or at the discretion of FDA. When granting such modifications, FDA may impose other reporting requirements to ensure the protection of public health.

(d) FDA may revoke or modify in writing an exemption, variance, or alternative reporting requirements if FDA determines that protection of the public health justifies the modification or a return to the requirements as stated in this part.

(e) Firms granted a reporting modification by FDA shall provide any reports or information required by that approval. The conditions of the approval will replace and supersede the reporting requirement specified in this part until such time that FDA revokes or modifies the alternative reporting requirements in accordance with paragraph (d) of this section.

(f) Manufacturers as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for serious adverse events that are not well-known or well-documented by the scientific community, including events related to contamination, or a

change in any ingredient or any manufacturing process.

(g) User facilities are exempt from submitting medical device reports concerning cigarettes and smokeless tobacco under this part.

[60 FR 63597, Dec. 11, 1995, as amended at 61 FR 44615, Aug. 28, 1996]

EFFECTIVE DATE NOTE: At 61 FR 44615, Aug. 28, 1996, § 803.19 was amended by adding paragraphs (f) and (g), effective Aug. 28, 1997.

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

§ 803.20 How to report.

(a) *Description of form.* There are two versions of the MEDWATCH form for individual reports of adverse events. FDA Form 3500 is available for use by health professionals and consumers for the submission of voluntary reports regarding FDA-regulated products. FDA Form 3500A is the mandatory reporting form to be used for submitting reports by user facilities and manufacturers of FDA-regulated products. The form has sections that must be completed by all reporters and other sections that must be completed only by the user facility or manufacturer.

(1) The front of FDA Form 3500A is to be filled out by all reporters. The front of the form requests information regarding the patient, the event, the device and “initial reporter” (i.e., the first person or entity that submitted the information to the user facility, manufacturer, or distributor).

(2) The back part of the form contains sections to be completed by user facilities and manufacturers. User facilities must complete section F; device manufacturers must complete sections G and H. Manufacturers are not required to recopy information submitted to them on a Form 3500A unless the information is being copied onto an electronic medium. If the manufacturer corrects or supplies information missing from the other reporter’s 3500A form, it should attach a copy of that form to the manufacturer’s report form. If the information from the other reporter’s 3500A form is complete and correct, the manufacturer can fill in

the remaining information on the same form.

(b) *Reporting standards.* (1) User facilities are required to submit MDR reports to:

(i) The device manufacturer and to FDA within 10 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a death; or

(ii) The manufacturer within 10 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury. Such reports shall be submitted to FDA if the device manufacturer is not known.

(2) [Reserved]

(3) Manufacturers are required to submit MDR reports to FDA:

(i) Within 30 days of becoming aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(ii) Within 30 days of becoming aware of information that reasonably suggests a device has malfunctioned and that device or a similar device marketed by the manufacturer would be likely to cause a death or serious injury if the malfunction were to recur; or

(iii) Within 5 days if required by § 803.53.

(c) *Information that reasonably suggests a reportable event occurred.* (1) Information that reasonably suggests that a device has or may have caused or contributed to an MDR reportable event (i.e., death, serious injury, and, for manufacturers, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur) includes any information, such as professional, scientific or medical facts and observations or opinions, that would reasonably suggest that a device has caused or may have caused or contributed to a reportable event.

(2) Entities required to report under this part do not have to report adverse events for which there is information that would cause a person who is qualified to make a medical judgment (e.g., a physician, nurse, risk manager, or biomedical engineer) to reach a reasonable conclusion that a device did not

cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Information which leads the qualified person to determine that a device-related event is or is not reportable must be contained in the MDR event files, as described in § 803.18.

§ 803.21 Reporting codes.

(a) FDA has developed a MEDWATCH Mandatory Reporting Form Coding Manual for use with medical device reports. This manual contains codes for hundreds of adverse events for use with FDA Form 3500A. The coding manual is available from the Division of Small Manufacturer Assistance, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850, FAX 301-443-8818.

(b) FDA may use additional coding of information on the reporting forms or modify the existing codes on an ad hoc or generic basis. In such cases, FDA will ensure that the new coding information is available to all reporters.

§ 803.22 When not to file.

(a) Only one medical device report from the user facility or manufacturer is required under this part if the reporting entity becomes aware of information from multiple sources regarding the same patient and same event.

(b) A medical device report that would otherwise be required under this section is not required if:

(1) The user facility or manufacturer determines that the information received is erroneous in that a device-related adverse event did not occur. Documentation of such reports shall be retained in MDR files for time periods specified in § 803.18.

(2) The manufacturer determines that the device was manufactured by another manufacturer. Any reportable event information that is erroneously sent to a manufacturer shall be forwarded to FDA, with a cover letter explaining that the device in question was not manufactured by that firm.

Subpart C—User Facility Reporting Requirements

§ 803.30 Individual adverse event reports; user facilities.

(a) *Reporting standard.* A user facility shall submit the following reports to the manufacturer or to FDA, or both, as specified below:

(1) *Reports of death.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall as soon as practicable, but not later than 10 work days after becoming aware of the information, report the information required by § 803.32 to FDA, on FDA Form 3500A, or an electronic equivalent as approved under § 803.14, and if the identity of the manufacturer is known, to the device manufacturer.

(2) *Reports of serious injury.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility, the facility shall, as soon as practicable but not later than 10 work days after becoming aware of the information, report the information required by § 803.32, on FDA Form 3500A or electronic equivalent, as approved under § 803.14, to the manufacturer of the device. If the identity of the manufacturer is not known, the report shall be submitted to FDA.

(b) *Information that is reasonably known to user facilities.* User facilities must provide all information required in this subpart C that is reasonably known to them. Such information includes information found in documents in the possession of the user facility and any information that becomes available as a result of reasonable followup within the facility. A user facility is not required to evaluate or investigate the event by obtaining or evaluating information that is not reasonably known to it.

§ 803.32 Individual adverse event report data elements.

User facility reports shall contain the following information, reasonably known to them as described in 803.30(b), which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

- (1) Patient name or other identifier;
- (2) Patient age at the time of event, or date of birth;
- (3) Patient gender; and
- (4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

- (1) Identification of adverse event or product problem;
- (2) Outcomes attributed to the adverse event, e.g., death; or serious injury, that is:

- (i) Life threatening injury or illness;
- (ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
- (iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

- (3) Date of event;
- (4) Date of report by the initial reporter;

(5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests including dates and laboratory data; and

(7) Description of other relevant history including pre-existing medical conditions.

(c) Device information (Block D) shall contain the following:

- (1) Brand name;
- (2) Type of device;
- (3) Manufacturer name and address;
- (4) Operator of the device (health professional, patient, lay user, other);
- (5) Expiration date;
- (6) Model number, catalog number, serial number, lot number, or other identifying number;
- (7) Date of device implantation (month, day, year);
- (8) Date of device explantation (month, day, year);

(9) Whether device was available for evaluation and whether device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and

(10) Concomitant medical products and therapy dates. (Do not list products that were used to treat the event.)

(d) Initial reporter information (Block E) shall contain the following:

(1) Name, address, and telephone number of the reporter who initially provided information to the user facility, manufacturer, or distributor;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether initial reporter also sent a copy of the report to FDA, if known.

(e) User facility information (Block F) shall contain the following:

(1) Whether reporter is a user facility;

(2) User facility number;

(3) User facility address;

(4) Contact person;

(5) Contact person's telephone number;

(6) Date the user facility became aware of the event (month, day, year);

(7) Type of report (initial or followup (if followup, include report number of initial report));

(8) Date of the user facility report (month, day, year);

(9) Approximate age of device;

(10) Event problem codes—patient code and device code (refer to FDA “Coding Manual For Form 3500A”);

(11) Whether a report was sent to FDA and the date it was sent (month, day, year);

(12) Location, where event occurred;

(13) Whether report was sent to the manufacturer and the date it was sent (month, day, year); and

(14) Manufacturer name and address; if available.

§ 803.33 Semiannual reports.

(a) Each user facility shall submit to FDA a semiannual report on FDA Form 3419, or electronic equivalent as approved by FDA under § 803.14. Semiannual reports shall be submitted by January 1 (for reports made July through December) and by July 1 (for reports made January through June) of each year. The semiannual report and

envelope shall be clearly identified and submitted to FDA with information that includes:

(1) User facility's HCFA provider number used for medical device reports, or number assigned by FDA for reporting purposes in accordance with § 803.3(dd);

(2) Reporting year and period, e.g., January through June or July through December;

(3) Facility's name and complete address;

(4) Total number of reports attached or summarized;

(5) Date of the semiannual report and the lowest and highest user facility report number of medical device reports submitted during the report period, e.g., 1234567890-1995-0001 through 1000;

(6) Name, position title, and complete address of the individual designated as the facility contact person responsible for reporting to FDA and whether that person is a new contact for that facility; and

(7) Information for each reportable event that occurred during the semiannual reporting period including:

(i) User facility report number;

(ii) Name and address of the device manufacturer;

(iii) Device brand name and common name;

(iv) Product model, catalog, serial and lot number;

(v) A brief description of the event reported to the manufacturer and/or FDA; and

(vi) Where the report was submitted, i.e., to FDA, manufacturer, distributor, etc.

(b) In lieu of submitting the information in paragraph (a)(7) of this section, a user facility may submit a copy of FDA Form 3500A, or an electronic equivalent as approved under section 803.14, for each medical device report submitted to FDA and/or manufacturers by that facility during the reporting period.

(c) If no reports are submitted to either FDA or manufacturers during these time periods, no semiannual report is required.

Subpart D [Reserved]

Subpart E—Manufacturer Reporting Requirements

§ 803.50 Individual adverse event reports; manufacturers.

(a) *Reporting standards.* Device manufacturers are required to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer:

(1) May have caused or contributed to a death or serious injury; or

(2) Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

(b) *Information that is reasonably known to manufacturers.* (1) Manufacturers must provide all information required in this subpart E that is reasonably known to them. FDA considers the following information to be reasonably known to the manufacturer:

(i) Any information that can be obtained by contacting a user facility, distributor and/or other initial reporter;

(ii) Any information in a manufacturer's possession; or

(iii) Any information that can be obtained by analysis, testing or other evaluation of the device.

(2) Manufacturers are responsible for obtaining and providing FDA with information that is incomplete or missing from reports submitted by user facilities, distributors, and other initial reporters. Manufacturers are also responsible for conducting an investigation of each event, and evaluating the cause of the event. If a manufacturer cannot provide complete information on an MDR report, it must provide a statement explaining why such information was incomplete and the steps taken to obtain the information. Any required information not available at the time of the report, which is obtained after the initial filing, must be provided by the manufacturer in a supplemental report under § 803.56.

§ 803.52 Individual adverse event report data elements.

Individual medical device manufacturer reports shall contain the following information, known or reasonably known to them as described in § 803.50(b), which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

- (1) Patient name or other identifier;
- (2) Patient age at the time of event, or date of birth;
- (3) Patient gender; and
- (4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

- (1) Adverse event or product problem;
- (2) Outcomes attributed to the adverse event, e.g., death; or serious injury, that is:
 - (i) Life threatening injury or illness;
 - (ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
 - (iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
- (3) Date of event;
- (4) Date of report by the initial reporter;

(5) Description of the event or problem to include a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Other relevant patient history including pre-existing medical conditions.

(c) Device information (Block D) shall contain the following:

- (1) Brand name;
- (2) Type of device;
- (3) Manufacturer name and address;
- (4) Operator of the device (health professional, patient, lay user, other);
- (5) Expiration date;
- (6) Model number, catalog number, serial number, lot number or other identifying number;
- (7) Date of device implantation (month, day, year);
- (8) Date of device explantation (month, day, year);

(9) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and

(10) Concomitant medical products and therapy dates. (Do not list products that were used to treat the event.)

(d) Initial reporter information (Block E) shall contain the following:

- (1) Name, address, and phone number of the reporter who initially provided information to the user facility, manufacturer, or distributor;
- (2) Whether the initial reporter is a health professional;
- (3) Occupation; and
- (4) Whether the initial reporter also sent a copy of the report to FDA, if known.

(e) All manufacturers (Block G) shall contain the following:

- (1) Contact office name and address and device manufacturing site;
- (2) Telephone number;
- (3) Report sources;
- (4) Date received by manufacturer (month, day, year);
- (5) Type of report being submitted (e.g., 5-day, initial, supplemental); and
- (6) Manufacturer report number.

(f) Device manufacturers (Block H) shall contain the following:

- (1) Type of reportable event (death, serious injury, malfunction, etc.);
- (2) Type of followup report, if applicable (e.g., correction, response to FDA request, etc.);
- (3) If the device was returned to the manufacturer and evaluated by the manufacturer, a summary of the evaluation. If no evaluation was performed, provide an explanation why no evaluation was performed;

(4) Device manufacture date (month, day, year);

(5) Was device labeled for single use;

(6) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA "Coding Manual for Form 3500A");

(7) Whether remedial action was taken and type;

(8) Whether use of device was initial, reuse, or unknown;

(9) Whether remedial action was reported as a removal or correction under section 519(f) of the act (list the correction/removal report number); and

(10) Additional manufacturer narrative; and/or

(11) Corrected data, including:

(i) Any information missing on the user facility report or distributor report, including missing event codes, or information corrected on such forms after manufacturer verification;

(ii) For each event code provided by the user facility under § 803.32(d)(10) or a distributor, a statement of whether the type of the event represented by the code is addressed in the device labeling; and

(iii) If any required information was not provided, an explanation of why such information was not provided and the steps taken to obtain such information.

§ 803.53 Five-day reports.

A manufacturer shall submit a 5-day report to FDA, on Form 3500A or electronic equivalent as approved by FDA under § 803.14 within 5 workdays of:

(a) Becoming aware that a reportable MDR event or events, from any information, including any trend analysis, necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health; or

(b) Becoming aware of an MDR reportable event for which FDA has made a written request for the submission of a 5-day report. When such a request is made, the manufacturer shall submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. The time period stated in the original written request can be extended by FDA if it is in the interest of the public health.

§ 803.55 Baseline reports.

(a) A manufacturer shall submit a baseline report on FDA Form 3417, or electronic equivalent as approved by FDA under § 803.14 for a device when the device model is first reported under § 803.50.

(b) Each baseline report shall be updated annually, on the anniversary month of the initial submission, after the initial baseline report is submitted. Changes to baseline information shall be reported in the manner described in

§ 803.56 (i.e., include only the new, changed, or corrected information in the appropriate portion(s) of the report form). Baseline reports shall contain the following:

(1) Name, complete address, and registration number of the manufacturer's reporting site. If the reporting site is not registered, FDA will assign a temporary registration number until the reporting site officially registers. The manufacturer will be informed of the temporary registration number;

(2) FDA registration number of each site where the device is manufactured;

(3) Name, complete address, and telephone number of the individual who has been designated by the manufacturer as its MDR contact and date of the report. For foreign manufacturers, a confirmation that the individual submitting the report is the agent of the manufacturer designated under § 803.58(a) is required;

(4) Product identification, including device family, brand name, generic name, model number, catalog number, product code and any other product identification number or designation;

(5) Identification of any device previously reported in a baseline report that is substantially similar (e.g., same device with a different model number, or same device except for cosmetic differences in color or shape) to the device being reported, including the identification of the previously reported device by model number, catalog number or other product identification, and the date of the baseline report for the previously reported device;

(6) Basis for marketing, including 510(k) premarket notification number or PMA number, if applicable, and whether the device is currently the subject of an approved post-market study under section 522 of the act;

(7) Date the device was initially marketed and, if applicable, the date on which the manufacturer ceased marketing the device;

(8) Shelf life, if applicable, and expected life of the device;

(9) The number of devices manufactured and distributed in the last 12 months and, an estimate of the number of devices in current use; and

(10) Brief description of any methods used to estimate the number of devices

distributed and the method used to estimate the number of devices in current use. If this information was provided in a previous baseline report, in lieu of resubmitting the information, it may be referenced by providing the date and product identification for the previous baseline report.

EFFECTIVE DATE NOTE: At 61 FR 39869, July 31, 1996, in § 803.55, paragraphs (b)(9) and (10) were stayed indefinitely.

§ 803.56 Supplemental reports.

When a manufacturer obtains information required under this part that was not provided because it was not known or was not available when the initial report was submitted, the manufacturer shall submit to FDA the supplemental information within 1 month following receipt of such information. In supplemental reports, the manufacturer shall:

(a) Indicate on the form and the envelope, that the reporting form being submitted is a supplemental report. If the report being supplemented is an FDA Form 3500A report, the manufacturer must select, in Item H-2, the appropriate code for the type of supplemental information being submitted;

(b) Provide the appropriate identification numbers of the report that will be updated with the supplemental information, e.g., original manufacturer report number and user facility report number, if applicable;

(c) For reports that cross reference previous reports, include only the new, changed, or corrected information in the appropriate portion(s) of the respective form(s).

§ 803.57 Annual certification.

(a) All manufacturers required to report under this section shall submit an annual certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under § 803.14. The date for submission of certification coincides with the date for the firm's annual registration, as designated in § 807.21 of this chapter. Foreign manufacturers shall submit their certification by the date on which they would be required to register under § 807.21 of this chapter if they were domestic manufacturers. The certification period will be the 12-month period ending

1 month before the certification date, except that the first certification period shall cover at least a 6-month period from the effective date of this section, ending 1 month before the certification date.

(b) The manufacturer shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's MDR reporting system. A manufacturer may determine, based upon its organizational structure, that one individual cannot oversee or have complete knowledge of the operation of the reporting system at all organizational components or manufacturing sites owned by the firm. In this circumstance, the firm may designate more than one certifying official, each of whom will sign a certification statement pertaining to his/her respective identified organizational component(s) or site(s), provided that all organizational components and sites are covered under a certification statement.

(c) The report shall contain the following information:

(1) Name, address, and FDA registration number or FDA assigned identification number of the reporting site and whether the firm is a manufacturer;

(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number or FDA assigned identification number for each manufacturing site covered by the certification and the number of reports submitted for devices manufactured at each site;

(4) A statement certifying that:

(i) The individual certifying for the firm has read the MDR requirements under this part;

(ii) The firm has established a system to implement MDR reporting;

(iii) Following the procedures of its MDR reporting system, the reporting site submitted the specified number of reports, or no reports, during the certification period; and

(iv) The certification is made to the best of the certifying official's knowledge and belief.

(d) The name of the manufacturer and the registration number submitted

under paragraph (c)(1) of this section shall be the same as the reporting site that submitted the reports required by §§ 803.52, 803.53, and 803.55. Multireporting site manufacturers who choose to certify centrally must identify the reporting sites, by registration number and name covered by the certification, and provide the information required by paragraphs (c)(2) and (c)(3) of this section for each reporting site.

[62 FR 13306, Mar. 20, 1997]

EFFECTIVE DATE NOTE: At 62 FR 13306, Mar. 20, 1997, § 803.57 was revised, effective May 19, 1997. For the convenience of the user, the superseded text is set forth as follows:

§ 803.57 Annual certification.

All manufacturers, including U.S. agents of foreign manufacturers required to report under this section, shall submit a certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under part 814 of this chapter. The date for submission of certification coincides with the date for the firm's annual registration, as designated in § 807.21 of this chapter. The certification period will be the 12-month period ending 1 month before the certification date. The reports shall contain the following information:

(a) Name, address, telephone number, and FDA registration number or FDA-assigned identification number of the firm and whether the firm is a manufacturer;

(b) A statement certifying that:

(1) The firm listed in paragraph (a) of this section has filed reports for all reportable events required under this section during the previous 12-month period. The firm shall also provide a numerical summary of MDR reports that it submitted to FDA during the preceding year; or

(2) The firm listed in paragraph (a) of this section did not receive reportable events for any devices manufactured by the firm during the previous 12-month period.

(c) Certification shall be made by the president, chief executive officer, U.S.-designated agent of a foreign manufacturer, or other official most directly responsible for the firm's operations; and

(d) Name of the manufacturer and registration numbers submitted under paragraph (a) of this section shall be the same as those used in submitting the reports required by §§ 803.52, 803.53 and 803.55. Multisite manufacturers who choose to certify centrally must identify the reporting sites, by registration number or FDA-assigned identification number and name covered by the certification, and provide the information required by paragraph (b) of this section for each reporting site.

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, § 803.57 was stayed indefinitely.

§ 803.58 Foreign manufacturers.

(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with § 807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and § 807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.

(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§ 803.50, 803.52, 803.53, 803.55, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of § 803.50;

(3) Certify in accordance with § 803.57;

(4) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(5) Maintain complaint files in accordance with § 803.18; and

(6) Register, list, and submit pre-market notifications in accordance with part 807 of this chapter.

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, § 803.58 was stayed indefinitely.

**PART 804—MEDICAL DEVICE
DISTRIBUTOR REPORTING**

Subpart A—General Provisions

Sec.

804.1 Scope.

804.3 Definitions.

804.9 Public availability of reports.

Subpart B—Reports and Records

804.25 Reports by distributors.

804.27 Where to submit a report.

804.28 Reporting form.

804.30 Annual certification.

804.31 Additional requirements.

804.32 Supplemental information.

§ 804.1

21 CFR Ch. I (4–1–97 Edition)

804.33 Alternative reporting requirements.

804.34 Written MDR procedures.

804.35 Files.

AUTHORITY: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

SOURCE: 58 FR 46519, Sept. 1, 1993, unless otherwise noted.

Subpart A—General Provisions

§ 804.1 Scope.

(a) FDA is requiring medical device distributors to report deaths, serious illnesses, and serious injuries that are attributed to medical devices. Distributors are also required to report certain device malfunctions and to submit a report to FDA annually certifying the number of medical device reports filed during the preceding year, or that no reports were filed. These reports enable FDA to protect the public health by helping to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for their intended use. In addition, device distributors are required to establish and maintain complaint files or incident files as described in § 804.35, and to permit any authorized FDA employee at all reasonable times to have access to, and to copy and verify, the records contained in this file. This part supplements, and does not supersede, other provisions of this subchapter, including the provisions of part 820 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 804.3 Definitions.

(a) Act means the Federal Food, Drug, and Cosmetic Act.

(b)-(c) [Reserved]

(d) *Distributor* means any person, including any person who imports a device into the United States, who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. One who repackages or otherwise changes the con-

tainer, wrapper, or labeling, is a manufacturer under § 804.3(k).

(e) *Distributor Report Number* means the number that uniquely identifies each report submitted by a distributor. Distributors who receive or submit reports shall use their seven digit FDA registration number, calendar year that the report is received, and a sequence number. For example, the complete number will appear as follows: 1234567–1991–0001. Distributor report numbers shall also be required on FDA form 3500A.

(f) *FDA* means the Food and Drug Administration.

(g) [Reserved]

(h) *Incident files* are those files containing documents or other information, which are related to adverse events that may have been caused by a device.

(i) *Information that reasonably suggests that there is a probability that a device has caused or contributed to a death or serious injury or serious illness* means information, including professional, scientific, or medical facts, observations, or opinions, which would cause a reasonable person to believe that a device caused or contributed to a death, serious injury, or serious illness.

(j) *Malfunction* means the failure of a device to meet any of its performance specifications or otherwise to perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It also may be shown by the circumstances that the device is, with the knowledge of such persons or their representatives, offered and used to perform a function for which it is neither labeled nor advertised.

(k) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device chemically, physically,

biologically, or by other procedures. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture, to the person who makes final delivery or sale to the ultimate user or consumer;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

(l) *MDR* means medical device report.

(m) *MDR reportable event* means:

(1) The event for which a distributor, other than an importer, required to report under this part has received or become aware of information that reasonably suggests that there is a probability that a device has caused or contributed to a death, serious illness, or serious injury; or

(2) The event for which an importer required to report under this part has received or become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(3) A malfunction, for which a distributor, other than an importer, required to report under this part has received or become aware of information that reasonably suggests that there is a probability that the device, if the malfunction were to recur, would be likely to cause or contribute to a death, serious illness, or serious injury; or

(4) A malfunction, for which an importer required to report under this part has received or become aware of information that reasonably suggests that a device has malfunctioned and that such device or a similar device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(n)-(p) [Reserved]

(q) *Permanent* means nonreversible impairment or damage.

(r) *Probability, probable, or probably* means, for purposes of this section, that a person would have reason to believe, based upon an analysis of the event and device, that the device has caused or contributed to an adverse event. This term does not signify statistical probability.

(s) A *remedial action* is any recall, repair, modification, adjustment, relabeling, destruction, inspection, patient monitoring, notification, or any other action relating to a device that is initiated by a distributor, in response to information that it receives or otherwise becomes aware of, that reasonably suggests that one of its marketed devices has caused or contributed to an MDR reportable event.

(t) *Serious illness* means an event that:

(1) Is life threatening;

(2) Results in permanent impairment of a body function or permanent damage to the body structure; or

(3) Necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(u) *Serious injury* means an event that:

(1) Is life threatening;

(2) Results in permanent impairment of a body function or permanent damage to a body structure, or

(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(v) [Reserved]

(w) *Work day* means Monday through Friday excluding Federal holidays. Federal holidays include New Year's Day, Martin Luther King Jr.'s Birthday, Presidents' Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day.

(x) Any term defined in section 201 of the act shall have the same definition unless otherwise defined in this part.

§ 804.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public

disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter; and

(2) Any personnel, medical, and similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under § 20.63 of this chapter; provided, that, except for the information under § 20.61 of this chapter, FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

Subpart B—Reports and Records

§ 804.25 Reports by distributors.

(a)(1) A distributor, other than an importer, shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 804.28 on FDA form 3500A as soon as practicable, but not later than 10 working days after the distributor receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that there is a probability that a device marketed by the distributor has caused or contributed to a death, serious illness, or serious injury.

(2) An importer shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 804.28 on FDA form 3500A as soon as practicable, but not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.

(b)(1) A distributor, other than an importer, shall submit to the manufacturer a report containing information required by § 804.28 on FDA form 3500A,

as soon as practicable, but not later than 10 working days after the distributor receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the distributor's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the distributor has malfunctioned and such information reasonably suggests that there is a probability that the device or any other device marketed by the distributor would cause a death, serious illness, or serious injury, if the malfunction were to recur.

(2) An importer shall submit to the manufacturer a report containing information required by § 804.28 on FDA form 3500A, as soon as practicable, but not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the distributor's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(c) Distributors as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for adverse events related to contamination.

[58 FR 46519, Sept. 1, 1993, as amended at 61 FR 44615, Aug. 28, 1996]

EFFECTIVE DATE NOTE: At 61 FR 44615, Aug. 28, 1996, § 804.25 was amended by adding paragraph (c), effective Aug. 28, 1997.

§ 804.27 Where to submit a report.

(a) Any telephone report required under this part shall be provided to 301-427-7500.

(b) Any facsimile report required under this part shall be provided to 301-881-6670.

(c) Any written report or additional information required under this part shall be submitted to:

Food and Drug Administration,

Food and Drug Administration, HHS

§ 804.30

Center for Devices and Radiological Health,
Distributor Report,
P.O. Box 3002,
Rockville, MD 20847-3002.

§ 804.28 Reporting form.

(a) Each distributor that submits a report on an MDR reportable event shall complete and submit the applicable portions of FDA form 3500A in so far as the information is known or should be known to the distributor, and submit it to FDA, and to the manufacturer as required by § 804.25.

(b) Each distributor shall submit the information requested on FDA form 3500A, including:

(1) Identification of the source of the report.

(i) Type of source that reported the event to the distributor (e.g., lay user owner; lay user lessee, hospital, nursing home, outpatient diagnostic facility, outpatient treatment facility, ambulatory surgical facility);

(ii) Distributor report number;

(iii) Name, address, and telephone number of the reporting distributor and the source that reported the event to the distributor; and

(iv) Name of the manufacturer of the device.

(2) Date information.

(i) The date of the occurrence of the event;

(ii) The date the source that reported the event to the distributor became aware of the event;

(iii) The date the event was reported to the manufacturer and/or FDA; and

(iv) The date of this report.

(3) The type of MDR reportable event, e.g., death, serious illness, serious injury, or malfunction, and whether an imminent hazard was involved;

(4) Patient information including age, sex, diagnosis, and medical status immediately prior to the event and after the event;

(5) Device information including brand and labeled name, generic name, model number or catalog number or other identifying numbers, serial number or lot number, purchase date, expected shelf life/expiration date (if applicable), whether the device was labeled for single use, and date of implant (if applicable);

(6) Maintenance/service information data including the last date of service performed on the device, where service was performed, whether service documentation is available, and whether service was in accordance with the service schedule;

(7) Whether the device is available for evaluation and, if not, the disposition of the device;

(8) Description of the event.

(i) Who was operating or using the device when the event occurred;

(ii) Whether the device was being used as labeled or as otherwise intended;

(iii) The location of the event;

(iv) Whether there was multi-patient involvement, and if so, how many patients were involved;

(v) A list of any other devices whose performance may have contributed to the event and their manufacturers, and the results of any analysis or evaluation with respect to such device (or a statement of why no analysis or evaluation was performed); and

(vi) A complete description of the event including, but not limited to, what happened, how the device was involved, the nature of the problem, patient followup/treatment required, and any environmental conditions that may have influenced the event.

(9) The results of any analysis of the device and the event, including:

(i) The method of evaluation or an explanation of why no evaluation was necessary or possible;

(ii) The results and conclusions of the evaluation;

(iii) The corrective actions taken; and

(iv) The degree of certainty concerning whether the device caused or contributed to the reported event;

(10) The name, title, address, telephone number, and signature of the person who prepared the report.

§ 804.30 Annual certification.

(a) All distributors required to report under this section shall submit an annual certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under § 803.14 of this chapter. The date for submission of certification coincides with the date for the firm's annual registration, as

designated in §807.21 of this chapter. The certification period will be the 12-month period ending 1 month before the certification date, except that the first certification period shall cover at least a 6-month period from the effective date of this section, ending 1 month before the certification date.

(b) The distributor shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's MDR reporting system. A distributor may determine, based upon its organizational structure, that one individual cannot oversee or have complete knowledge of the operation of the reporting system at all organizational components or distribution sites owned by the firm. In this circumstance, the firm may designate more than one certifying official (one for each component or site), each of whom will sign a certification statement pertaining to their respective identified organizational component(s) or site(s), provided that all organizational components and sites are covered under a certification statement.

(c) The report shall contain the following information:

(1) Name, address, and FDA registration number or FDA assigned identification number of the firm;

(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number or FDA assigned identification number for the distributor covered by the certification, and the number of reports submitted for devices distributed by the distributor;

(4) A statement certifying that:

(i) The individual certifying for the firm has read the MDR requirements under part 804;

(ii) The firm has established a system to implement MDR reporting;

(iii) Following the procedures of its MDR reporting system, the firm submitted the specified number of reports, or no reports, during the certification period; and

(iv) The certification is made to the best of the certifying official's knowledge and belief.

[62 FR 13306, Mar. 20, 1997]

EFFECTIVE DATE NOTE: At 62 FR 13306, Mar. 20, 1997, §804.30 was added, effective May 19, 1997.

§804.31 Additional requirements.

Requests for additional information. If FDA determines that the protection of the public health requires information in addition to that included in the medical device reports submitted to FDA under this part, the distributor shall, upon FDA's request, submit such additional information. Any request by FDA under this section shall state the reason or purpose for which the information is being requested, and specify a due date for the submission of such information.

§804.32 Supplemental information.

(a) Only one MDR is required under this part if the distributor becomes aware, from more than one source, of information concerning the same patient and the same event.

(b) An MDR that would otherwise be required under this section is not required by the distributor if:

(1) The distributor determines that the information received is erroneous in that a death, serious injury, serious illness, or the malfunction did not occur; or

(2) The distributor determines that the information received is erroneous in that the device that is the subject of the information was distributed by another distributor. A distributor shall forward to FDA any report that is erroneously sent to the distributor, with a cover letter explaining that the product in question is not distributed by that firm.

(c) A report or information submitted by a distributor under this part (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, the establishment submitting the report, or employees thereof, caused or contributed to a death, serious injury, serious illness, or malfunction. A distributor need not admit, and may deny, that the report or information submitted under this part constitutes an admission that the

device, the party submitting the report, or employees thereof, caused or contributed to a death or serious injury, serious illness, or malfunction.

§804.33 Alternative reporting requirements.

(a) Distributors may request exemptions from any or all of the reporting requirements in this part. These requests are required to be in writing and to include both the information necessary to identify the firm and device and an explanation why the request is justified.

(b) FDA may grant a distributor, in writing, an exemption from any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time periods. In granting such exemptions, FDA may impose other reporting requirements to ensure the protection of public health and safety. FDA may also authorize the use of alternative reporting media such as magnetic tape or disk, in lieu of FDA forms.

(c) FDA may revoke alternative reporting options, in writing, if FDA determines that protection of the public health justifies a return to the requirements as stated in this part.

§804.34 Written MDR procedures.

Device distributors shall maintain and implement written MDR procedures in the following areas:

(a) Training and education programs informing employees about obligations under this section, including how to identify and report MDR reportable events;

(b) Internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, a standardized review process/procedure for determining when an event meets the criteria for reporting under this part, and timely transmission of complete MDR's to FDA and/or manufacturers; and

(c) Documentation and recordkeeping requirements for:

(1) Information that may be the subject of an MDR;

(2) All MDR's and information submitted to FDA and manufacturers;

(3) Information that facilitates the submission of certification reports; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by FDA.

§804.35 Files.

(a) A device distributor shall establish a device complaint file in accordance with §820.198 of this chapter and maintain a record of any information, including any written or oral communication, received by the distributor concerning all events that were considered for possible reporting under this part. Device incident records shall be prominently identified as such and shall be filed by device. The file shall also contain a copy of any MDR along with any additional information submitted to FDA under this part. A distributor shall maintain records that document the submission of copies of MDR's to manufacturers.

(b) A device distributor shall retain copies of the records required to be maintained under this section for a period of 2 years from the date that the report or additional information is submitted to FDA under §804.25, or for a period of time equivalent to the design and expected life of the device, whichever is greater, even if the distributor has ceased to distribute the device that is the subject of the report or the additional information.

(c) A device distributor shall maintain the device complaint files established under this section at the distributor's principal business establishment. A distributor that is also a manufacturer may maintain the file at the same location as the manufacturer maintains its complaint file under §§820.180 and 820.198 of this chapter. A device distributor shall permit any authorized FDA employee, during all reasonable times, to have access to, and to copy and verify, the records required by this part.

**PART 805—CARDIAC PACEMAKER
REGISTRY**

Subpart A—General Provisions

Sec.

805.1 Scope.

805.3 Definitions.

Subpart B—Submission of Information

805.10 Submission of information by physicians and providers.

805.20 How to submit information.

805.25 Confidentiality.

AUTHORITY: Sec. 1862(h) of the Social Security Act and sec. 2304(d) of the Deficit Reduction Act (42 U.S.C. 1395y(h), 1395y note).

SOURCE: 52 FR 27763, July 23, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 805.1 Scope.

(a) This part provides for a nationwide cardiac pacemaker registry and requires any physician and any provider of services who requests or receives payment from Medicare for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads to submit certain information to the registry. If the physician or the provider of services does not submit the information according to this part and 42 CFR 409.19(a) and 410.64(a), HCFA, which administers the Medicare program, will deny payment to the physician or the provider. FDA will use the information submitted to the registry to track the performance of permanent pacemakers and pacemaker leads and to perform studies and analyses regarding the use of the devices, and to transmit data to HCFA to assist HCFA in administering the Medicare program and to other Department of Health and Human Services' components to carry out statutory responsibilities.

(b) Information submitted to the registry by a physician or a provider of services (and any release by FDA or HCFA of that information) does not necessarily reflect a conclusion by the submitter, FDA, or HCFA that the information constitutes an admission that a pacemaker device or lead failed to operate within its performance specifications. A submitter need not admit, and may deny, that the information submitted to the registry constitutes an admission that the pacemaker device or lead failed to operate within its performance specifications.

(c) References in this part to regulatory sections of the Code of Federal

Regulations are to chapter I of title 21, unless otherwise noted.

§ 805.3 Definitions.

(a) *FDA* means the Food and Drug Administration.

(b) *HCFA* means the Health Care Financing Administration.

(c) A *pacemaker* or *pacemaker device* is a device that produces periodic electrical impulses to stimulate the heart. It consists of two basic components: a pulse generator and one or more leads. See § 870.3610 for a more detailed definition.

(d) A *pacemaker lead* is a flexible, insulated wire connected at one end to a pacemaker's pulse generator and at the other end to the heart. It transmits electrical stimuli to and from the heart. See § 870.3680(b) for a more detailed definition.

(e) A *physician* is a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by applicable laws of the State in which he or she performs such function or actions. (This definition includes an osteopathic practitioner.)

(f) A *PRO* is a Utilization and Quality Control Peer Review Organization that contracts with the Secretary of Health and Human Services to review health care services funded by the Medicare program to determine whether those services are reasonable, medically necessary, furnished in the appropriate setting, and are of a quality which meets professionally recognized standards.

(g) A *provider* is a hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or a hospice that has in effect an agreement to participate in Medicare.

(h) A *warranty* is an express or implied guarantee, under contract or State law, of the integrity of a pacemaker device or pacemaker lead and of the manufacturer's responsibility for the repair or replacement of defective parts of a pacemaker device or pacemaker lead.

(i) Any terms defined in section 201 of the Federal Food, Drug, and Cosmetic Act will have that definition.

Subpart B—Submission of Information

§ 805.10 Submission of information by physicians and providers.

A physician or a provider of services that requests or receives payment from Medicare for the implantation, removal, or replacement of a permanent cardiac pacemaker device or pacemaker lead shall submit the following information on a specified form to HCFA for inclusion in the pacemaker registry provided for by FDA under § 805.1:

- (a) Provider number.
- (b) Patient's health insurance claim number (HICN).
- (c) Patient's name.
- (d) Date of the procedure.
- (e) Identification number (used by PRO's) and name of the physician who ordered the procedure.
- (f) Identification number (used by PRO's) and name of the operating physician.
- (g) For each device (pulse generator, atrial lead, ventricular lead) implanted during the procedure about which the report is being made: the name of the manufacturer, model number, serial number, and the warranty expiration date.
- (h) For each device (pulse generator, atrial lead, ventricular lead) removed or replaced during the procedure about which the report is being made: the name of the manufacturer; model number; serial number; the warranty expiration date, if known; the date the device was initially implanted, if known; whether a device that was replaced was left in the body; if the device was not left in the body, whether it was returned to the manufacturer.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0234)

§ 805.20 How to submit information.

Information shall be submitted to the registry in the form and manner required under general instructions of the Medicare program (see 42 CFR 409.19(a) and 410.64(a)).

§ 805.25 Confidentiality.

- (a) FDA and HCFA will keep confidential, and will not reveal to the

public, any specific information that identifies by name a recipient of any pacemaker device or lead or that would otherwise identify a specific recipient.

(b) Public disclosure of all other information under this part will be governed by the Freedom of Information Act (5 U.S.C. 552), the Privacy Act of 1974 (5 U.S.C. 552a), the Department of Health and Human Services' public information regulations (45 CFR part 5), FDA's public information regulations (21 CFR part 20), and HCFA's public information regulations (subpart B of 42 CFR part 401).

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

Subpart A—General Provisions

Sec.

807.3 Definitions.

Subpart B—Procedures for Domestic Device Establishments

- 807.20 Who must register and submit a device list.
- 807.21 Times for establishment registration and device listing.
- 807.22 How and where to register establishments and list devices.
- 807.25 Information required or requested for establishment registration and device listing.
- 807.26 Amendments to establishment registration.
- 807.30 Updating device listing information.
- 807.31 Additional listing information.
- 807.35 Notification of registrant.
- 807.37 Inspection of establishment registration and device listings.
- 807.39 Misbranding by reference to establishment registration or to registration number.

Subpart C—Registration Procedures for Foreign Device Establishments

- 807.40 Establishment registration and device listing for U.S. agents of foreign manufacturers of devices.

Subpart D—Exemptions

- 807.65 Exemptions for device establishments.

Subpart E—Premarket Notification Procedures

- 807.81 When a premarket notification submission is required.
- 807.85 Exemption from premarket notification.
- 807.87 Information required in a premarket notification submission.
- 807.90 Format of a premarket notification submission.
- 807.92 Content and format of a 510(k) summary.
- 807.93 Content and format of a 510(k) statement.
- 807.94 Format of class III certification.
- 807.95 Confidentiality of information.
- 807.97 Misbranding by reference to premarket notification.
- 807.100 FDA action on a premarket notification.

AUTHORITY: Secs. 301, 501, 502, 510, 513, 515, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374).

SOURCE: 42 FR 42526, Aug. 23, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 807.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Commercial distribution* means any distribution of a device intended for human use which is held or offered for sale but does not include the following:

(1) Internal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company;

(2) Any distribution of a device intended for human use which has in effect an approved exemption for investigational use pursuant to section 520(g) of the act and part 812 of this chapter; or

(3) Any distribution of a device, before the effective date of part 812 of this chapter, that was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and that is classified into class III under section 513(f) of the act: *Provided*, That the device is intended solely for investigational use, and under section 501(f)(2)(A) of the act the device is not required to have an approved premarket approval application as provided in section 515 of the act.

(c) *Establishment* means a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed.

(d) *Manufacture, preparation, propagation, compounding, assembly, or processing* of a device means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act. These terms include the following activities:

(1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer;

(2) Distribution of domestic or imported devices; or

(3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications.

(e) *Official correspondent* means the person designated by the owner or operator of an establishment as responsible for the following:

(1) The annual registration of the establishment;

(2) Contact with the Food and Drug Administration for device listing;

(3) Maintenance and submission of a current list of officers and directors to the Food and Drug Administration upon the request of the Commissioner;

(4) The receipt of pertinent correspondence from the Food and Drug Administration directed to and involving the owner or operator and/or any of the firm's establishments; and

(5) The annual certification of medical device reports required by § 804.30 of this chapter or forwarding the certification form to the person designated by the firm as responsible for the certification.

(f) *Owner or operator* means the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment.

(g) *Distributor* means any person who furthers the marketing of a device from the original place of manufacture, whether domestic or imported, to the

person who makes final delivery or sale to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.

(h) Any term defined in section 201 of the act shall have that meaning.

(i) *Restricted device* means a device for which the Commissioner, by regulation under §801.109 of this chapter or otherwise under section 520(e) of the act, has restricted sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use the device or upon such other conditions as the Commissioner may prescribe.

(j) *Classification name* means the term used by the Food and Drug Administration and its classification panels to describe a device or class of devices for purposes of classifying devices under section 513 of the act.

(k) *Representative sampling of advertisements* means typical advertising material that gives the promotional claims made for the device.

(l) *Representative sampling of any other labeling* means typical labeling material (excluding labels and package inserts) that gives the promotional claims made for the device.

(m) *Material change* includes any change or modification in the labeling or advertisements that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common or usual or proprietary name, declared ingredients or components, intended use, contraindications, warnings, or instructions for use. Changes that are not material may include graphic layouts, grammar, or correction of typographical errors which do not change the content of the labeling, changes in lot number, and, for devices where the biological activity or known composition differs with each lot produced, the labeling containing the actual values for each lot.

(n) *510(k) summary* (summary of any information respecting safety and effectiveness) means a summary, submitted under section 513(i) of the act, of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence

can be based. Safety and effectiveness information refers to safety and effectiveness data and information supporting a finding of substantial equivalence, including all adverse safety and effectiveness information.

(o) *510(k) statement* means a statement, made under section 513(i) of the act, asserting that all information in a premarket notification submission regarding safety and effectiveness will be made available within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information to be made available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret or confidential commercial information, as defined in §20.61 of this chapter.

(p) *Class III certification* means a certification that the submitter of the 510(k) has conducted a reasonable search of all known information about the class III device and other similar, legally marketed devices.

(q) *Class III summary* means a summary of the types of safety and effectiveness problems associated with the type of device being compared and a citation to the information upon which the summary is based. The summary must be comprehensive and describe the problems to which the type of device is susceptible and the causes of such problems.

(r) *U.S.-designated agent* means the person, residing in the United States, designated and authorized by the owner or operator of a foreign manufacturer who exports devices into the United States and is responsible for:

- (1) Submitting MDR reports,
- (2) Submitting annual certifications,
- (3) Acting as the official correspondent,
- (4) Submitting registration information,
- (5) Submitting device listing information, and

(6) Submitting premarket notifications on behalf of the foreign manufacturer.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37997, Aug. 25, 1978; 57 FR 18066, Apr. 28, 1992; 58 FR 46522, Sept. 1, 1993; 59 FR 64295, Dec. 14, 1994; 60 FR 63606, Dec. 11, 1995]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, in §807.3, paragraph (r) was stayed indefinitely.

Subpart B—Procedures for Domestic Device Establishments

§ 807.20 Who must register and submit a device list.

(a) An owner or operator of an establishment not exempt under section 510(g) of the act or Subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use is required to register and to submit listing information for those devices in commercial distribution, except that listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term "device" includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator is required to register its name, places of business, and all establishments and to list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who:

(1) Initiates or develops specifications for a device that is to be manufactured by a second party for commercial distribution by the person initiating specifications;

(2) Manufactures for commercial distribution a device either for itself or for another person. However, a person who only manufactures devices according to another person's specifications, for commercial distribution by the per-

son initiating specifications, is not required to list those devices.

(3) Repackages or relabels a device;

(4) Distributors;

(5) Manufactures components or accessories which are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g., blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

(6) Acts as the U.S.-designated agent as defined in §807.3(r).

(b) No registration or listing fee is required. Registration or listing does not constitute an admission or agreement or determination that a product is a device within the meaning of section 201(h) of the act.

(c) Distributors of domestic or imported devices must register and fulfill their listing obligations as described in §807.22(c) of this part. Distributors with multiple sites may submit one registration for all sites or submit a registration for each site. If a multisite distributor chooses to file one registration, the registration must be from the principal business establishment which maintains the MDR complaint files.

(d) Registration and listing requirements shall not pertain to any person who:

(1) Manufacturers devices for another party who both initiated the specifications and commercially distributes the device;

(2) Sterilizes devices on a contract basis for other registered facilities who commercially distribute the devices.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37997, Aug. 25, 1978; 58 FR 46522, Sept. 1, 1993; 60 FR 63606, Dec. 11, 1995]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, in §807.20, paragraph (a)(6) was stayed indefinitely.

§ 807.21 Times for establishment registration and device listing.

(a) An owner or operator of an establishment who has not previously entered into an operation defined in §807.20 shall register within 30 days after entering into such an operation

Food and Drug Administration, HHS

§ 807.25

and submit device listing information at that time. An owner or operator of an establishment shall update its registration information annually within 30 days after receiving registration forms from FDA. FDA will mail form FDA-2891a to the owners or operators of registered establishments according to a schedule based on the first letter of the name of the owner or operator. The schedule is as follows:

First letter of owner or operator name	Date FDA will mail forms
A, B, C, D, E	March.
F, G, H, I, J, K, L, M	June.
N, O, P, Q, R	August.
S, T, U, V, W, X, Y, Z	November.

(b) Owners or operators of all registered establishments shall update their device listing information every June and December or, at their discretion, at the time the change occurs.

[58 FR 46522, Sept. 1, 1993]

§ 807.22 How and where to register establishments and list devices.

(a) The first registration of a device establishment shall be on Form FDA-2891 (Initial Registration of Device Establishment). Forms are available upon request from the Office of Compliance, Center for Devices and Radiological Health (HFZ-307), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, or from Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on Form FDD-2891a (Annual Registration of Device Establishment), which will be furnished by FDA to establishments whose registration for that year was validated under § 807.35(a). The forms will be mailed to the owner or operators of all establishments via the official correspondent in accordance with the schedule as described in § 807.21(a). The completed form shall be mailed to the address designated in this paragraph 30 days after receipt from FDA.

(b) The initial listing of devices and subsequent June and December updatings shall be on form FD-2892 (Medical Device Listing). Forms are obtainable upon request as described in paragraph (a) of this section. A separate form FD-2892 shall be submitted for each device or device class listed

with the Food and Drug Administration. Devices having variations in physical characteristics such as size, package, shape, color, or composition should be considered to be one device: *Provided*, The variation does not change the function or intended use of the device. In lieu of form FD-2892, tapes for computer input or hard copy computer output may be submitted if equivalent in all elements of information as specified in form FD-2892. All formats proposed for use in lieu of form FD-2892 require initial review and approval by the Food and Drug Administration.

(c) The listing obligations of the distributor are satisfied as follows:

(1) The distributor is not required to submit a form FDA-2892 for those devices for which such distributor did not initiate or develop the specifications for the device or repackaging or relabel the device. However, the distributor shall submit, for each device, the name and address of the manufacturer. Distributors shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are the distributors; and

(2) The distributor shall update the information required by paragraphs (c)(1) of this section at the intervals specified in § 807.30.

[43 FR 37997, Aug. 25, 1978, as amended at 58 FR 46522, Sept. 1, 1993; 60 FR 63606, Dec. 11, 1995]

§ 807.25 Information required or requested for establishment registration and device listing.

(a) Form FD-2891 and Form FD-2891(a) are the approved forms for initially providing the information required by the act and for providing annual registration, respectively. The required information includes the name and street address of the device establishment, including post office ZIP Code, all trade names used by the establishment, and the business trading name of the owner or operator of such establishment.

(b) The owner or operator shall identify the device activities of the establishment such as manufacturing, repackaging, or distributing devices.

(c) Each owner or operator is required to maintain a listing of all officers, directors, and partners for each establishment he registers and to furnish this information to the Food and Drug Administration upon request.

(d) Each owner or operator shall provide the name of an official correspondent who will serve as a point of contact between the Food and Drug Administration and the establishment for matters relating to the registration of device establishments and the listing of device products. All future correspondence relating to registration, including requests for the names of partners, officers, and directors, will be directed to this official correspondent. In the event no person is designated by the owner or operator, the owner or operator of the establishment will be the official correspondent.

(e) The designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual under section 301(p) or any other provision of the act.

(f) Form FD-2892 is the approved form for providing the device listing information required by the act. This required information includes the following:

(1) The identification by classification name and number, proprietary name, and common or usual name of each device being manufactured, prepared, propagated, compounded, or processed for commercial distribution that has not been included in any list of devices previously submitted on form FD-2892.

(2) The Code of Federal Regulations citation for any applicable standard for the device under section 514 of the act or section 358 of the Public Health Service Act.

(3) The assigned Food and Drug Administration number of the approved application for each device listed that is subject to section 505, 507, or 515 of the act.

(4) The name, registration number, and establishment type of every domestic or foreign device establishment under joint ownership and control of the owner or operator at which the device is manufactured, repackaged, or relabeled.

(5) Whether the device, as labeled, is intended for distribution to and use by the general public.

(6) Other general information requested on form FD-2892, i.e., (i) if the submission refers to a previously listed device, as in the case of an update, the document number from the initial listing document for the device, (ii) the reason for submission, (iii) the date on which the reason for submission occurred, (iv) the date that the form FD-2892 was completed, (v) the owner's or operator's name and identification number.

(7) Labeling or other descriptive information (e.g., specification sheets or catalogs) adequate to describe the intended use of a device when the owner or operator is unable to find on the Food and Drug Administration list in the device listing package, an appropriate classification name for the device.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37998, Aug. 25, 1978; 58 FR 46523, Sept. 1, 1993]

§807.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, or location of an operation defined in §807.3(c) shall be submitted on Form FD-2891(a). This information shall be submitted within 30 days of such changes. Changes in the names of officers and/or directors of the corporation(s) shall be filed with the establishment's official correspondent and shall be provided to the Food and Drug Administration upon receipt of a written request for this information.

§807.30 Updating device listing information.

(a) Form FD-2892 shall be used to update device listing information. The preprinted original document number of each form FD-2892 on which the device was initially listed shall appear in block 2 on the form subsequently used to update the listing information for the device and on any correspondence related to the device.

(b) An owner or operator shall update the device listing information during each June and December or, at its discretion, at the time the change occurs.

Conditions that require updating and information to be submitted for each of these updates are as follows:

(1) If an owner or operator introduces into commercial distribution a device identified with a classification name not currently listed by the owner or operator, then the owner or operator must submit form FD-2892 containing all the information required by § 807.25(f).

(2) If an owner or operator discontinues commercial distribution of all devices in the same device class, i.e., with the same classification name, the owner or operator must submit form FD-2892 containing the original document number of the form FD-2892 on which the device class was initially listed, the reason for submission, the date of discontinuance, the owner or operator's name and identification number, the classification name and number, the proprietary name, and the common or usual name of the discontinued device.

(3) If commercial distribution of a discontinued device identified on a form FD-2892 filed under paragraph (b)(2) of this section is resumed, the owner or operator must submit on form FD-2892 a notice of resumption containing: the original document number of the form initially used to list that device class, the reason for submission, date of resumption, and all other information required by § 807.25(f).

(4) If one or more classification names for a previously listed device with multiple classification names has been added or deleted, the owner or operator must supply the original document number from the form FD-2892 on which the device was initially listed and a supplemental sheet identifying the names of any new or deleted classification names.

(5) Other changes to information on form FD-2892 will be updated as follows:

(i) Whenever a change occurs only in the owner or operator name (block 6) or number (block 7), e.g., whenever one company's device line is purchased by another owner or operator, it will not be necessary to supply a separate form FD-2892 for each device. In such cases, the new owner or operator must follow the procedures in § 807.26 and submit a

letter informing the Food and Drug Administration of the original document number from form FD-2892 on which each device was initially listed for those devices affected by the change in ownership.

(ii) The owner or operator must also submit update information whenever changes occur to the responses to the questions in blocks 12, 12a, 13, 13a, and 14 on form FD-2892, or whenever establishment registration numbers, establishment names, and/or activities are added to or deleted from blocks 15, 16, and 17 of form FD-2892. The owner or operator must supply the original document number from the form FD-2892 on which the device was initially listed, the reason for submission, and all other information required by § 807.25(f).

(6) Updating is not required if the above information has not changed since the previously submitted list. Also, updating is not required if changes occur in proprietary names, in common or usual names (blocks 10 and 11 of form FD-2892), or to supplemental lists of unclassified components or accessories.

[43 FR 37998, Aug. 25, 1978]

§ 807.31 Additional listing information.

(a) Each owner or operator shall maintain a historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing, as follows:

(1) For each device subject to section 514 or 515 of the act that is not a restricted device, a copy of all labeling for the device;

(2) For each restricted device, a copy of all labeling and advertisements for the device;

(3) For each device that is neither restricted nor subject to section 514 or 515 of the act, a copy of all labels, package inserts, and a representative sampling of any other labeling.

(b) In addition to the requirements set forth in paragraph (a) of this section, each owner or operator shall maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing.

(c) Each owner or operator may discard labeling and advertisements from the historical file 3 years after the date of the last shipment of a discontinued device by an owner or operator.

(d) Location of the file:

(1) Currently existing systems for maintenance of labeling and advertising may be used for the purpose of maintaining the historical file as long as the information included in the systems fulfills the requirements of this section, but only if the labeling and advertisements are retrievable in a timely manner.

(2) The contents of the historical file may be physically located in more than one place in the establishment or in more than one establishment provided there exists joint ownership and control among all the establishments maintaining the historical file. If no joint ownership and control exists, the registered establishment must provide the Food and Drug Administration with a letter authorizing the establishment outside its control to maintain the historical file.

(e) Each owner or operator shall be prepared to submit to the Food and Drug Administration, only upon specific request, the following information:

(1) For a device subject to section 514 or 515 of the act that is not a restricted device, a copy of all labeling for the device.

(2) For a device that is a restricted device, a copy of all labeling for the device, a representative sampling of advertisements for the device, and for good cause, a copy of all advertisements for a particular device. A request for all advertisements will, where feasible, be accompanied by an explanation of the basis for such request.

(3) For a device that is neither a restricted device, nor subject to section 514 or 515 of the act, the label and package insert for the device and a representative sampling of any other labeling for the device.

(4) For a particular device, a statement of the basis upon which the registrant has determined that the device is not subject to section 514 or 515 of the act.

(5) For a particular device, a statement of the basis upon which the reg-

istrant has determined the device is not a restricted device.

(6) For a particular device, a statement of the basis for determining that the product is a device rather than a drug.

(7) For a device that the owner or operator has manufactured for distribution under a label other than its own, the names of all distributors for whom it has been manufactured.

[43 FR 37999, Aug. 25, 1978, as amended at 51 FR 33033, Sept. 18, 1986]

§ 807.35 Notification of registrant.

(a) The Commissioner will provide to the official correspondent, at the address listed on the form, a validated copy of Form FD-2891 or Form FD-2891(a) (whichever is applicable) as evidence of registration. A permanent registration number will be assigned to each device establishment registered in accordance with these regulations.

(b) Owners and operators of device establishments who also manufacture or process blood or drug products at the same establishment shall also register with the Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research, as appropriate. Blood products shall be listed with the Center for Biologics Evaluation and Research, Food and Drug Administration, pursuant to Part 607 of this chapter; drug products shall be listed with the Center for Drug Evaluation and Research, Food and Drug Administration, pursuant to Part 207 of this chapter.

(c) Although establishment registration and device listing are required to engage in the device activities described in § 807.20, validation of registration and the assignment of a device listing number in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37999, Aug. 25, 1978; 53 FR 11252, Apr. 6, 1988]

§ 807.37 Inspection of establishment registration and device listings.

(a) A copy of the forms FD-2891 and FD-2891a filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, Department of Health and Human Services, 1390 Piccard Dr., Rockville, MD 20850. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request, verification of registration number or location of a registered establishment will be provided.

(b)(1) The following information filed under the device listing requirements will be available for public disclosure:

- (i) Each form FD-2892 submitted;
- (ii) All labels submitted;
- (iii) All labeling submitted;
- (iv) All advertisements submitted;

(v) All data or information that has already become a matter of public knowledge.

(2) Requests for device listing information identified in paragraph (b)(1) of this section should be directed to the Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, Department of Health and Human Services, 1390 Piccard Dr., Rockville, MD 20850.

(3) Requests for device listing information not identified in paragraph (b)(1) of this section shall be submitted and handled in accordance with Part 20 of this chapter.

[43 FR 37999, Aug. 25, 1978, as amended at 53 FR 11252, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

§ 807.39 Misbranding by reference to establishment registration or to registration number.

Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.

Subpart C—Registration Procedures for Foreign Device Establishments**§ 807.40 Establishment registration and device listing for U.S. agents of foreign manufacturers of devices.**

(a) Each foreign device manufacturer who exports devices into the United States shall designate a person as their U.S.-designated agent, who is responsible for:

- (1) Submitting MDR reports,
- (2) Submitting annual certifications,
- (3) Acting as the official correspondent,
- (4) Submitting registration information,
- (5) Submitting device listing information, and
- (6) Submitting premarket notifications.

(b) The foreign manufacturer shall provide FDA with a statement of authorization for their U.S.-designate to perform MDR reporting duties under part 803 of this chapter, and to register, list, and submit premarket notifications under this part. The foreign manufacturer must provide this statement of authorization along with the name, address, and telephone number of the person initially designated, or any subsequent person designated as the U.S.-designated agent, within 5 days of the initial or subsequent designation. Information shall be sent to the Center for Devices and Radiological Health, Medical Device Reporting, Food and Drug Administration, P.O. Box 3002, Rockville, MD 20847-3002.

(c) The U.S.-designated agent of a foreign device manufacturer that exports devices into the United States is required to register the foreign manufacturer's establishments or places of business, and to list the foreign manufacturer's devices, in accordance with subpart B of this part, unless exempt under subpart D of this part, and to submit premarket notifications in accordance with subpart E of this part. The information submitted shall be in the English language.

[60 FR 63606, Dec. 11, 1995]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, § 807.40 was stayed indefinitely.

Subpart D—Exemptions

§ 807.65 Exemptions for device establishments.

The following classes of persons are exempt from registration in accordance with § 807.20 under the provisions of section 510(g) (1), (2), and (3) of the act, or because the Commissioner has found, under section 510(g)(4) of the act, that such registration is not necessary for the protection of the public health:

(a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under the provisions of this part.

(b) A manufacturer of devices to be used solely for veterinary purposes.

(c) A manufacturer of general purpose articles such as chemical reagents or laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses.

(d) Licensed practitioners, including physicians, dentists, and optometrists, who manufacture or otherwise alter devices solely for use in their practice.

(e) Pharmacies, surgical supply outlets, or other similar retail establishments making final delivery or sale to the ultimate user. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name, e.g., a properly labeled health aid such as an elastic bandage or crutch, indicating “distributed by” or “manufactured for” followed by the name of the pharmacy.

(f) Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution.

(g) [Reserved]

(h) Carriers by reason of their receipt, carriage, holding or delivery of devices in the usual course of business as carriers.

(i) Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived

from the use of a device; for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic x-ray systems, and personnel from a hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device.

(j) Distributors of cigarettes or smokeless tobacco as defined in part 897 of this chapter.

[42 FR 42526, Aug. 23, 1977, as amended at 58 FR 46523, Sept. 1, 1993; 61 FR 44615, Aug. 28, 1996]

EFFECTIVE DATE NOTE: At 61 FR 44615, Aug. 28, 1996, § 807.65 was amended by adding paragraph (j), effective Aug. 28, 1997.

Subpart E—Premarket Notification Procedures

§ 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to, (i) a device in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a)(1) of this section.

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in

design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

(b) A premarket notification under this subpart is not required for a device for which a premarket approval application under section 515 of the act, or for which a petition to reclassify under section 513(f)(2) of the act, is pending before the Food and Drug Administration.

(c) In addition to complying with the requirements of this part, owners or operators of device establishments that manufacture radiation-emitting electronic products, as defined in §1000.3 of this chapter, shall comply with the reporting requirements of Part 1002 of this chapter.

§ 807.85 Exemption from premarket notification.

(a) A device is exempt from the premarket notification requirements of this subpart if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and the device meets one of the following conditions:

(1) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or

(2) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons).

(b) A distributor who places a device into commercial distribution for the first time under his own name and a repackager who places his own name on a device and does not change any other

labeling or otherwise affect the device shall be exempted from the premarket notification requirements of this subpart if:

(1) The device was in commercial distribution before May 28, 1976; or

(2) A premarket notification submission was filed by another person.

§ 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed

for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(j) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(k) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the

original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0281)

[42 FR 42526, Aug 23, 1977, as amended at 57 FR 18066, Apr. 28, 1992; 59 FR 64295, Dec. 14, 1994]

§ 807.90 Format of a premarket notification submission.

Each premarket notification submission pursuant to this part shall be submitted in accordance with this section. Each submission shall:

(a)(1) For devices regulated by the Center for Devices and Radiological Health, be addressed to the Food and Drug Administration, Center for Devices and Radiological Health (HFZ-401), 1390 Piccard Dr., Rockville, MD 20850.

(2) For devices regulated by the Center for Biologics Evaluation and Research, be addressed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Division of Product Certification (HFB-240), 8800 Rockville Pike, Bethesda, MD 20892.

(3) All inquiries regarding a premarket notification submission should be in writing and sent to one of the addresses above.

(b) Be bound into a volume or volumes, where necessary.

(c) Be submitted in duplicate on standard size paper, including the original and two copies of the cover letter.

(d) Be submitted separately for each product the manufacturer intends to market.

(e) Designated “510(k) Notification” in the cover letter.

[42 FR 42526, Aug. 23, 1977, as amended at 53 FR 11252, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

§ 807.92 Content and format of a 510(k) summary.

(a) A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. FDA will accept summaries as well as amendments thereto until such time as FDA issues a determination of substantial equivalence. All 510(k) summaries shall contain the following information:

(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process;

(4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;

(5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended.

If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled; and

(6) If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.

(b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:

(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence;

(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence; and

(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.

(c) The summary should be in a separate section of the submission, beginning on a new page and ending on a page not shared with any other section of the premarket notification submission, and should be clearly identified as a “510(k) summary.”

(d) Any other information reasonably deemed necessary by the agency.

[57 FR 18066, Apr. 28, 1992, as amended at 59 FR 64295, Dec. 14, 1994]

§ 807.93 Content and format of a 510(k) statement.

(a)(1) A 510(k) statement submitted as part of a premarket notification shall state as follows:

I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(2) The statement in paragraph (a)(1) of this section should be signed by the certifier, made on a separate page of the premarket notification submission, and clearly identified as “510(k) statement.”

(b) All requests for information included in paragraph (a) of this section shall be made in writing to the certifier, whose name will be published by FDA on the list of premarket notification submissions for which substantial equivalence determinations have been made.

(c) The information provided to requestors will be a duplicate of the premarket notification submission, including any adverse information, but excluding all patient identifiers, and trade secret and confidential commercial information as defined in § 20.61 of this chapter.

[59 FR 64295, Dec. 14, 1994]

§ 807.94 Format of a class III certification.

(a) A class III certification submitted as part of a premarket notification shall state as follows:

I certify, in my capacity as (position held in company), of (company name), that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the (type of device). I further certify that I am aware of the types of problems to which the (type of device) is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about the (type of device) is complete and accurate.

(b) The statement in paragraph (a) of this section should be signed by the certifier, clearly identified as “class III certification,” and included at the beginning of the section of the premarket notification submission that sets forth the class III summary.

[59 FR 64296, Dec. 14, 1994]

§ 807.95 Confidentiality of information.

(a) The Food and Drug Administration will disclose publicly whether there exists a premarket notification submission under this part:

(1) Where the device is on the market, i.e., introduced or delivered for introduction into interstate commerce for commercial distribution;

(2) Where the person submitting the premarket notification submission has disclosed, through advertising or any other manner, his intent to market the device to scientists, market analysts, exporters, or other individuals who are not employees of, or paid consultants to, the establishment and who are not in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy; or

(3) Where the device is not on the market and the intent to market the device has not been so disclosed, except where the submission is subject to an exception under paragraph (b) or (c) of this section.

(b) The Food and Drug Administration will not disclose publicly the existence of a premarket notification submission for a device that is not on the market and where the intent to

market the device has not been disclosed for 90 days from the date of receipt of the submission, if:

(1) The person submitting the premarket notification submission requests in the submission that the Food and Drug Administration hold as confidential commercial information the intent to market the device and submits a written certification to the Commissioner:

(i) That the person considers his intent to market the device to be confidential commercial information;

(ii) That neither the person nor, to the best of his knowledge, anyone else, has disclosed through advertising or any other manner, his intent to market the device to scientists, market analysts, exporters, or other individuals, except employees of, or paid consultants to, the establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;

(iii) That the person will immediately notify the Food and Drug Administration if he discloses the intent to market the device to anyone, except employees of, or paid consultants to, the establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;

(iv) That the person has taken precautions to protect the confidentiality of the intent to market the device; and

(v) That the person understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q); and

(2) The Commissioner agrees that the intent to market the device is confidential commercial information.

(c) Where the Commissioner determines that the person has complied with the procedures described in paragraph (b) of this section with respect to a device that is not on the market and where the intent to market the device has not been disclosed, and the Commissioner agrees that the intent to market the device is confidential commercial information, the Commissioner will not disclose the existence of the submission for 90 days from the date of its receipt by the agency. In addition, the Commissioner will continue not to

disclose the existence of such a submission for the device for an additional time when any of the following occurs:

(1) The Commissioner requests in writing additional information regarding the device pursuant to § 807.87(h), in which case the Commissioner will not disclose the existence of the submission until 90 days after the Food and Drug Administration's receipt of a complete premarket notification submission;

(2) The Commissioner determines that the device intended to be introduced is a class III device and cannot be marketed without premarket approval or reclassification, in which case the Commissioner will not disclose the existence of the submission unless a petition for reclassification is submitted under section 513(f)(2) of the act and its existence can be disclosed under § 860.5(d) of this chapter; or

(d) FDA will make a 510(k) summary of the safety and effectiveness data available to the public within 30 days of the issuance of a determination that the device is substantially equivalent to another device. Accordingly, even when a 510(k) submitter has complied with the conditions set forth in paragraphs (b) and (c) of this section, confidentiality for a premarket notification submission cannot be granted beyond 30 days after FDA issues a determination of equivalency.

(e) Data or information submitted with, or incorporated by reference in, a premarket notification submission (other than safety and effectiveness data that have not been disclosed to the public) shall be available for disclosure by the Food and Drug Administration when the intent to market the device is no longer confidential in accordance with this section, unless exempt from public disclosure in accordance with Part 20 of this chapter. Upon final classification, data and information relating to safety and effectiveness of a device classified in class I (general controls) or class II (performance standards) shall be available for public disclosure. Data and information relating to safety and effectiveness of a device classified in class III (premarket approval) that have not been released to

§ 807.97

the public shall be retained as confidential unless such data and information become available for release to the public under § 860.5(d) or other provisions of this chapter.

[42 FR 42526, Aug. 23, 1977, as amended at 53 FR 11252, Apr. 6, 1988; 57 FR 18067, Apr. 28, 1992; 59 FR 64296, Dec. 14, 1994]

§ 807.97 Misbranding by reference to premarket notification.

Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

§ 807.100 FDA action on a premarket notification.

(a) After review of a premarket notification, FDA will:

(1) Issue an order declaring the device to be substantially equivalent to a legally marketed predicate device;

(2) Issue an order declaring the device to be not substantially equivalent to any legally marketed predicate device;

(3) Request additional information; or

(4) Advise the applicant that the premarket notification is not required. Until the applicant receives an order declaring a device substantially equivalent, the applicant may not proceed to market the device.

(b) FDA will determine that a device is substantially equivalent to a predicate device using the following criteria:

(1) The device has the same intended use as the predicate device; and

(2) The device:

(i) Has the same technological characteristics as the predicate device; or

21 CFR Ch. I (4–1–97 Edition)

(ii)(A) Has different technological characteristics, such as a significant change in the materials, design, energy source, or other features of the device from those of the predicate device;

(B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the Commissioner, that demonstrates that the device is as safe and as effective as a legally marketed device; and

(C) Does not raise different questions of safety and effectiveness than the predicate device.

(3) The predicate device has not been removed from the market at the initiative of the Commissioner of Food and Drugs or has not been determined to be misbranded or adulterated by a judicial order.

[57 FR 58403, Dec. 10, 1992]

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

Subpart A—General Provisions

Sec.

808.1 Scope.

808.3 Definitions.

808.5 Advisory opinions.

Subpart B—Exemption Procedures

808.20 Application.

808.25 Procedures for processing an application.

808.35 Revocation of an exemption.

Subpart C—Listing of Specific State and Local Exemptions

808.53 Arizona.

808.55 California.

808.57 Connecticut.

808.59 Florida.

808.61 Hawaii.

808.67 Kentucky.

808.69 Maine.

808.71 Massachusetts.

808.73 Minnesota.

808.74 Mississippi.

808.77 Nebraska.

808.80 New Jersey.

808.81 New Mexico.

808.82 New York.

808.85 Ohio.

808.87 Oregon.

808.88 Pennsylvania.

Food and Drug Administration, HHS

§ 808.1

808.89 Rhode Island.
808.93 Texas.
808.97 Washington.
808.98 West Virginia.
808.101 District of Columbia.

AUTHORITY: Secs. 520, 521, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j, 360k, 371).

SOURCE: 43 FR 18665, May 2, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 808.1 Scope.

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not “requirements applicable to a device” within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements.

If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging

fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(10) Part 820 of this chapter (21 CFR part 820) (CGMP requirements) does not preempt remedies created by States or Territories of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

[43 FR 18665, May 2, 1978, as amended at 45 FR 67336, Oct. 10, 1980; 61 FR 52654, Oct. 7, 1996]

EFFECTIVE DATE NOTE: At 61 FR 52654, Oct. 7, 1996, in § 808.1, paragraph (d)(10) was added, effective June 1, 1997.

§ 808.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Compelling local conditions* includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

(c) *More stringent* refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the act.

(d) *Political subdivision* or *locality* means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

(e) *State* means a State, American Samoa, the Canal Zone, the Commonwealth of Puerto Rico, the District of Columbia, Guam, Johnston Island, Kingman Reef, Midway Island, the Trust Territory of the Pacific Islands, the Virgin Islands, and Wake Island.

(f) *Substantially identical* to refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.

§ 808.5 Advisory opinions.

(a) Any State, political subdivision, or other interested person may request an advisory opinion from the Commissioner with respect to any general matter concerning preemption of State or local device requirements or with respect to whether the Food and Drug Administration regards particular State or local requirements, or proposed requirements, as preempted.

(1) Such an advisory opinion may be requested and may be granted in accordance with § 10.85 of this chapter.

(2) The Food and Drug Administration, in its discretion and after consultation with the State or political subdivision, may treat a request by a State or political subdivision for an advisory opinion as an application for exemption from preemption under § 808.20.

(b) The Commissioner may issue an advisory opinion relating to a State or local requirement on his own initiative when he makes one of the following determinations:

(1) A requirement with respect to a device for which an application for exemption from preemption has been submitted under § 808.20 is not preempted by section 521(a) of the act because it is: (i) Equal to or substantially identical to a requirement under the act applicable to the device, or (ii) is not a requirement within the meaning of section 521 of the act and therefore is not preempted;

(2) A proposed State or local requirement with respect to a device is not eligible for exemption from preemption because the State or local requirement has not been issued in final form. In such a case, the advisory opinion may indicate whether the proposed requirement would be preempted and, if it would be preempted, whether the Food and Drug Administration would propose to grant an exemption from preemption;

(3) Issuance of such an advisory opinion is in the public interest.

Subpart B—Exemption Procedures**§ 808.20 Application.**

(a) Any State or political subdivision may apply to the Food and Drug Administration for an exemption from preemption for any requirement that it has enacted and that is preempted. An exemption may only be granted for a requirement that has been enacted, promulgated, or issued in final form by the authorized body or official of the State or political subdivision so as to have the force and effect of law. However, an application for exemption may be submitted before the effective date of the requirement.

(b) An application for exemption shall be in the form of a letter to the Commissioner of Food and Drugs and shall be signed by an individual who is authorized to request the exemption on behalf of the State or political subdivision. An original and two copies of the letter and any accompanying material, as well as any subsequent reports or correspondence concerning an application, shall be submitted to the Dockets

Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr. Rockville, MD 20857. The outside wrapper of any application, report, or correspondence should indicate that it concerns an application for exemption from preemption of device requirements.

(c) For each requirement for which an exemption is sought, the application shall include the following information to the fullest extent possible, or an explanation of why such information has not been included:

(1) Identification and a current copy of any statute, rule, regulation, or ordinance of the State or political subdivision considered by the State or political subdivision to be a requirement which is preempted, with a reference to the date of enactment, promulgation, or issuance in final form. The application shall also include, where available, copies of any legislative history or background materials pertinent to enactment, promulgation, or issuance of the requirement, including hearing reports or studies concerning development or consideration of the requirement. If the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall furnish copies of such judicial or administrative interpretations.

(2) A comparison of the requirement of the State or political subdivision and any applicable Federal requirements to show similarities and differences.

(3) Information on the nature of the problem addressed by the requirement of the State or political subdivision.

(4) Identification of which (or both) of the following bases is relied upon for seeking an exemption from preemption:

(i) The requirement is more stringent than a requirement applicable to a device under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or material showing how and why the requirement of the State or political subdivision is more stringent than requirements under the act.

(ii) The requirement is required by compelling local conditions, and com-

pliance with the requirement would not cause the device to be in violation of any applicable requirement under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or material showing why compliance with the requirement of the State or political subdivision would not cause a device to be in violation of any applicable requirement under the act and why the requirement is required by compelling local conditions. The application shall also explain in detail the compelling local conditions that justify the requirement.

(5) The title of the chief administrative or legal officers of that State or local agency that has primary responsibility for administration of the requirement.

(6) When requested by the Food and Drug Administration, any records concerning administration of any requirement which is the subject of an exemption or an application for an exemption from preemption.

(7) Information on how the public health may be benefitted and how interstate commerce may be affected, if an exemption is granted.

(8) Any other pertinent information respecting the requirement voluntarily submitted by the applicant.

(d) If litigation regarding applicability of the requirement is pending, the State or political subdivision may so indicate in its application and request expedited action on such application.

[43 FR 18665, May 2, 1978; 43 FR 22010, May 23, 1978, as amended at 49 FR 3646, Jan. 30, 1984; 59 FR 14365, Mar. 28, 1994]

§ 808.25 Procedures for processing an application.

(a) Upon receipt of an application for an exemption from preemption submitted in accordance with § 808.20, the Commissioner shall notify the State or political subdivision of the date of such receipt.

(b) If the Commissioner finds that an application does not meet the requirements of § 808.20, he shall notify the State or political subdivision of the deficiencies in the application and of the

opportunity to correct such deficiencies. A deficient application may be corrected at any time.

(c) After receipt of an application meeting the requirements of §808.20, the Commissioner shall review such application and determine whether to grant or deny an exemption from preemption for each requirement which is the subject of the application. The Commissioner shall then issue in the FEDERAL REGISTER a proposed regulation either to grant or to deny an exemption from preemption. The Commissioner shall also issue in the FEDERAL REGISTER a notice of opportunity to request an oral hearing before the Commissioner or the Commissioner's designee.

(d) A request for an oral hearing may be made by the State or political subdivision or any other interested person. Such request shall be submitted to the Dockets Management Branch within the period of time prescribed in the notice and shall include an explanation of why an oral hearing, rather than submission of written comments only, is essential to the presentation of views on the application for exemption from preemption and the proposed regulation.

(e) If a timely request for an oral hearing is made, the Commissioner shall review such a request and may grant a legislative-type informal oral hearing pursuant to Part 15 of this chapter by publishing in the FEDERAL REGISTER a notice of the hearing in accordance with §15.20 of this chapter. The scope of the oral hearing shall be limited to matters relevant to the application for exemption from preemption and the proposed regulation. Oral or written presentations at the oral hearing which are not relevant to the application shall be excluded from the administrative record of the hearing.

(f) If a request for hearing is not timely made or a notice of appearance is not filed pursuant to §15.21 of this chapter, the Commissioner shall consider all written comments submitted and publish a final rule in accordance with paragraph (g) of this section.

(g)(1) The Commissioner shall review all written comments submitted on the proposed rule and the administrative record of the oral hearing, if an oral

hearing has been granted, and shall publish in the FEDERAL REGISTER a final rule in Subpart C of this part identifying any requirement in the application for which exemption from preemption is granted, or conditionally granted, and any requirement in the application for which exemption from preemption is not granted.

(2) The Commissioner may issue a regulation granting or conditionally granting an application for an exemption from preemption for any requirement if the Commissioner makes either of the following findings:

(i) The requirement is more stringent than a requirement applicable to the device under the act;

(ii) The requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any requirement applicable to the device under the act.

(3) The Commissioner may not grant an application for an exemption from preemption for any requirement with respect to a device if the Commissioner determines that the granting of an exemption would not be in the best interest of public health, taking into account the potential burden on interstate commerce.

(h) An advisory opinion pursuant to §808.5 or a regulation pursuant to paragraph (g) of this section constitutes final agency action.

§808.35 Revocation of an exemption.

(a) An exemption from preemption pursuant to a regulation under this part shall remain effective until the Commissioner revokes such exemption.

(b) The Commissioner may by regulation, in accordance with §808.25, revoke an exemption from preemption for any of the following reasons:

(1) An exemption may be revoked upon the effective date of a newly established requirement under the act which, in the Commissioner's view, addresses the objectives of an exempt requirement and which is described, when issued, as preempting a previously exempt State or local requirement.

(2) An exemption may be revoked upon a finding that there has occurred a change in the bases listed in

§ 808.20(c)(4) upon which the exemption was granted.

(3) An exemption may be revoked if it is determined that a condition placed on the exemption by the regulation under which the exemption was granted has not been met or is no longer being met.

(4) An exemption may be revoked if a State or local jurisdiction fails to submit records as provided in § 808.20(c)(6).

(5) An exemption may be revoked if a State or local jurisdiction to whom the exemption was originally granted requests revocation.

(6) An exemption may be revoked if it is determined that it is no longer in the best interests of the public health to continue the exemption.

(c) An exemption that has been revoked may be reinstated, upon request from the State or political subdivision, if the Commissioner, in accordance with the procedures in § 808.25, determines that the grounds for revocation are no longer applicable except that the Commissioner may permit abbreviated submissions of the documents and materials normally required for an application for exemption under § 808.20.

Subpart C—Listing of Specific State and Local Exemptions

§ 808.53 Arizona.

The following Arizona medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act:

(a) Arizona Revised Statutes, Chapter 17, sections 36–1901.7(s) and 36–1901.7(t).

(b) Arizona Code of Revised Regulations, Title 9, Article 3, sections R9–16–303 and R9–16–304.

[45 FR 67336, Oct. 10, 1980]

§ 808.55 California.

(a) The following California medical device requirements are enforceable notwithstanding section 521 of the act because the Food and Drug Administration exempted them from preemption under section 521(b) of the act:

Business and Professions Code sections 3365 and 3365.6.

(b) The following California medical device requirements are preempted by section 521 of the act, and FDA has denied them an exemption from preemption:

(1) Sherman Food, Drug, and Cosmetic Law (Division 21 of the California Health and Safety Code), sections 26207, 26607, 26614, 26615, 26618, 26631, 26640, and 26641, to the extent that they apply to devices.

(2) Sherman Food, Drug, and Cosmetic Law, section 26463(m) to the extent that it applies to hearing aids.

(3) Business and Professions Code section 2541.3, to the extent that it requires adoption of American National Standards Institute standards Z–80.1 and Z–80.2.

[45 FR 67324, Oct. 10, 1980]

§ 808.57 Connecticut.

The following Connecticut medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: Connecticut General Statutes, sections 20–403 and 20–404.

[45 FR 67336, Oct. 10, 1980]

§ 808.59 Florida.

The following Florida medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act:

(a) Florida Statutes, section 468.135(5).

(b) Florida Administrative Code, section 10D–48.25(26).

[45 FR 67336, Oct. 10, 1980]

§ 808.61 Hawaii.

(a) The following Hawaii medical device requirements are enforceable notwithstanding section 521 of the act, because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: Hawaii Revised Statutes, chapter 451A, § 14.1, subsection (a) with respect to medical examination of a child 10 years of age or under, and subsection (c).

Food and Drug Administration, HHS

§ 808.77

(b) The following Hawaii medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemption from preemption: Hawaii Revised Statutes, chapter 451A, §14.1, subsection (a) to the extent that it requires a written authorization by a physician and does not allow adults to waive this requirement for personal, as well as religious reasons, and subsection (b).

[50 FR 30699, July 29, 1985; 50 FR 32694, Aug. 14, 1985]

§808.67 Kentucky.

The following Kentucky medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Kentucky Revised Statutes, section 334.200(1).

[45 FR 67336, Oct. 10, 1980]

§808.69 Maine.

(a) The following Maine medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Maine Revised Statutes Annotated, Title 32, section 1658-C, on the condition that, in enforcing this requirement, Maine apply the definition of “used hearing aid” in §801.420(a)(6) of this chapter.

(b) The following Maine medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Maine Revised Statutes Annotated, Title 32, section 1658-D and the last sentence of section 1658-E.

[45 FR 67336, Oct. 10, 1980]

§808.71 Massachusetts.

(a) The following Massachusetts medical device requirements are enforceable notwithstanding section 521 of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) Massachusetts General Laws, Chapter 93, Section 72, to the extent

that it requires a hearing test evaluation for a child under the age of 18.

(2) Massachusetts General Laws, Chapter 93, Section 74, except as provided in paragraph (6) of the Section, on the condition that, in enforcing this requirement, Massachusetts apply the definition of “used hearing aid” in §801.420(a)(6) of this chapter.

(b) The following Massachusetts medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act.

(1) Massachusetts General Laws, Chapter 93, Section 72, except as provided in paragraph (a) of this section.

(2) Massachusetts General Laws, Chapter 93, Section 74, to the extent that it requires that the sales receipt contain a statement that State law requires a medical examination and a hearing test evaluation before the sale of a hearing aid.

[45 FR 67326, Oct. 10, 1980]

§808.73 Minnesota.

The following Minnesota medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Minnesota Statutes, sections 145.43 and 145.44.

[45 FR 67336, Oct. 10, 1980]

§808.74 Mississippi.

The following Mississippi medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Mississippi Code, section 73-14-3(g)(9).

[45 FR 67336, Oct. 10, 1980]

§808.77 Nebraska.

(a) The following Nebraska medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Nebraska Revised Statutes, section 71-4712(2)(c)(vi).

(b) The following Nebraska medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Nebraska Revised Statutes, section 71-4712(2)(c)(vii).

[45 FR 67336, Oct. 10, 1980]

§ 808.80 New Jersey.

(a) The following New Jersey medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) New Jersey Statutes Annotated, section 45:9A-23 on the condition that, in enforcing this requirement, New Jersey apply the definition of “used hearing aid” in § 801.420(a)(6) of this chapter;

(2) New Jersey Statutes Annotated, sections 45:9A-24 and 45:9A-25;

(3) Chapter 3, Section 5 of the Rules and Regulations adopted pursuant to New Jersey Statutes Annotated 45:9A-1 et seq. except as provided in paragraph (b) of this section.

(b) The following New Jersey medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Chapter 3, Section 5 of the Rules and Regulations adopted pursuant to New Jersey Statutes Annotated 45:9A-1 et seq. to the extent that it requires testing to be conducted in an environment which meets or exceeds the American National Standards Institute S3.1 Standard.

[45 FR 67337, Oct. 10, 1980]

§ 808.81 New Mexico.

The following New Mexico medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: New Mexico Statutes Annotated, section 67-36-16(F).

[45 FR 67337, Oct. 10, 1980]

§ 808.82 New York.

(a) The following New York medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) General Business Law, Article 37, sections 784(3) and (4).

(2) Official Compilation of Codes, Rules and Regulations of the State of New York, Chapter V, Title 19, Subchapter G, section 191.10 and section 191.11(a) on the condition that, in enforcing these requirements, New York apply the definition of “used hearing aid” in § 801.420(a)(6) of this chapter and section 191.11(b), (c), (d), and (e).

(b) The following New York medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemptions from preemption under section 521(b) of the act:

(1) General Business Law, Article 37, section 784.1.

(2) Official Compilation of Codes, Rules and Regulations of the State of New York, Chapter V, Title 19, Subchapter G, sections 191.6, 191.7, 191.8, and 191.9.

[45 FR 67337, Oct. 10, 1980]

§ 808.85 Ohio.

(a) The following Ohio medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Ohio Revised Code, section 4747.09, the first two sentences with respect to disclosure of information to purchasers on the condition that, in enforcing these requirements, Ohio apply the definition of “used hearing aid” in § 801.420(a)(6) of this chapter.

(b) The following Ohio medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Ohio Revised Code, section 4747.09, the last two sentences with respect to medical examination of children.

[45 FR 67337, Oct. 10, 1980]

§ 808.87 Oregon.

(a) The following Oregon medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: Oregon Revised Statutes, section 694.036 on the condition that, in enforcing this requirement, Oregon apply the definition of “used hearing aid” in § 801.420(a)(6) of this chapter.

(b) The following Oregon medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act: Oregon Revised Statutes, sections 694.136(6) and (7).

[45 FR 67337, Oct. 10, 1980, as amended at 53 FR 11252, Apr. 6, 1988]

§ 808.88 Pennsylvania.

(a) The following Pennsylvania medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: 35 Purdon’s Statutes 6700, section 504(4) on the condition that, in enforcing this requirement, Pennsylvania apply the definition of “used hearing aid” in § 801.420(a)(6) of this chapter; section 506; and, section 507(2).

(b) The following Pennsylvania medical device requirement is preempted by section 521(a) of the act and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: 35 Purdon’s Statutes 6700, section 402.

[45 FR 67326, Oct. 10, 1980]

§ 808.89 Rhode Island.

The following Rhode Island medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Rhode Island General Laws, Section 5-49-2.1, and Section 2.2, to the extent that Section 2.2 requires hearing aid dispensers

to keep copies of the certificates of need.

[45 FR 67337, Oct. 10, 1980]

§ 808.93 Texas.

(a) The following Texas medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Vernon’s Civil Statutes, Article 4566, section 14(b) on the condition that, in enforcing this requirement, Texas apply the definition of “used hearing aid” in § 801.420(a)(6) of this chapter.

(b) The following Texas medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Vernon’s Civil Statutes, Article 4566, section 14(d).

[45 FR 67337, Oct. 10, 1980]

§ 808.97 Washington.

(a) The following Washington medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Revised Code of Washington 18.35.110(2)(e)(i) and (iii) on the condition that it is enforced in addition to the applicable requirements of this chapter.

(b) The following Washington medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Revised Code of Washington 18.35.110(2)(e)(ii).

[45 FR 67337, Oct. 10, 1980]

§ 808.98 West Virginia.

(a) The following West Virginia medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption: West Virginia Code, sections 30-26-14 (b) and (c) and section 30-26-15(a) on the condition that in enforcing section 30-26-15(a) West Virginia apply the definition of “used hearing aid” in § 801.420(a)(6) of this chapter.

(b) The following West Virginia medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: West Virginia Code, section 30–26–14(a).

[45 FR 67337, Oct. 10, 1980, as amended at 53 FR 35314, Sept. 13, 1988]

§ 808.101 District of Columbia.

(a) The following District of Columbia medical device requirements are enforceable, notwithstanding section 521 of the act, because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) Act 2–79, section 5, to the extent that it requires an audiological evaluation for children under the age of 18.

(2) Act 2–79, section 6, on the condition that in enforcing section 6(a)(5), the District of Columbia apply the definition of “used hearing aid” in § 801.420(a)(6) of this chapter.

(b) The following District of Columbia medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Act 2–79, section 5, except as provided in paragraph (a) of this section.

[46 FR 59236, Dec. 4, 1981]

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

Subpart A—General Provisions

Sec.

809.3 Definitions.

809.4 Confidentiality of submitted information.

809.5 Exemption from batch certification requirements for in vitro antibiotic susceptibility devices subject to section 507 of the act.

809.6 Conditions on the effectiveness of exemptions of antibiotic susceptibility devices from batch certification requirements.

Subpart B—Labeling

809.10 Labeling for in vitro diagnostic products.

Subpart C—Requirements for Manufacturers and Producers

809.20 General requirements for manufacturers and producers of in vitro diagnostic products.

AUTHORITY: Secs. 301, 501, 502, 505, 507, 512, 513, 514, 518, 519, 520, 701, 702, 704, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 355, 357, 360b, 360c, 360d, 360h, 360i, 360j, 371, 372, 374, 381).

Subpart A—General Provisions

§ 809.3 Definitions.

(a) *In vitro diagnostic products* are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act.

(b) A *product class* is all those products intended for use for a particular determination or for a related group of determinations or products with common or related characteristics or those intended for common or related uses. A class may be further divided into subclasses when appropriate.

(c) [Reserved]

(d) *Act* means the Federal Food, Drug, and Cosmetic Act.

[41 FR 6903, Feb. 13, 1976, as amended at 45 FR 7484, Feb. 1, 1980]

§ 809.4 Confidentiality of submitted information.

Data and information submitted under § 809.10(c) that are shown to fall within the exemption established in § 20.61 of this chapter shall be treated as confidential by the Food and Drug Administration and any person to

whom the data and information are referred. The Food and Drug Administration will determine whether information submitted will be treated as confidential in accordance with the provisions of Part 20 of this chapter.

[45 FR 7484, Feb. 1, 1980]

§ 809.5 Exemption from batch certification requirements for in vitro antibiotic susceptibility devices subject to section 507 of the act.

(a) Antibiotic susceptibility devices subject to section 507 of the act are exempt from the batch certification requirements of Part 431 of this chapter if the following conditions are met:

(1) The antibiotic susceptibility device is approved for marketing under an appropriate antibiotic application.

(2) The antibiotic susceptibility device is packaged and labeled for dispensing in accordance with the applicable regulation (monograph) in this chapter except where other labeling has been approved in an applicable antibiotic application.

(3) The bulk antibiotic drug used in preparing the antibiotic susceptibility device meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application.

(4) The antibiotic susceptibility device meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application.

(b) For each antibiotic susceptibility device subject to an exemption under this section, an approved antibiotic application is regarded to be an approved premarket approval application under section 515 of the act.

(c) Nothing in this section prevents a manufacturer from applying for batch certification of an antibiotic susceptibility device as provided in section 507(c) of the act.

(d) All exemptions from batch certification requirements for antibiotic susceptibility devices under this section

are subject to the conditions of effectiveness under § 809.6.

[47 FR 39160, Sept. 7, 1982, as amended at 53 FR 11252, Apr. 6, 1988]

§ 809.6 Conditions on the effectiveness of exemptions of antibiotic susceptibility devices from batch certification requirements.

(a) If at any time after an exemption from batch certification requirements for an antibiotic susceptibility device has been granted, the Commissioner finds on the basis of new information before the agency with respect to such exempted device evaluated together with the evidence available to the agency when such exemption was granted, that certification of each batch is necessary to ensure its safety and efficacy of use, the Commissioner shall act immediately to revoke all exemptions from batch certification requirements granted for such device.

(b) If the Commissioner finds that the person granted an exemption from batch certification requirements for an antibiotic susceptibility device has failed to comply with the requirements of section 507 of the act and the regulations promulgated thereunder; or if the Commissioner finds that the requirements of § 809.5 have not been met; or if the Commissioner finds that the petition for exemption from batch certification contains any false statements of fact, the Commissioner may revoke the exemption from batch certification requirements immediately and require batch certification of the device until such person shows adequate cause why the exemption from batch certification requirements should be reinstated.

(c) If the Commissioner repeals or suspends an exemption from batch certification requirements for an antibiotic susceptibility device, a notice to that effect and the reasons therefor will be published in the FEDERAL REGISTER.

(d) Any person who contests the revocation or suspension or denial of reinstatement of an exemption from batch certification requirements for an antibiotic susceptibility device shall have an opportunity for a regulatory hearing before the Food and Drug Administration under Part 16 of this chapter.

[47 FR 39160, Sept. 7, 1982]

Subpart B—Labeling

§ 809.10 Labeling for in vitro diagnostic products.

(a) The label for an in vitro diagnostic product shall state the following information, except where such information is not applicable, or as otherwise specified in a standard for a particular product class. Section 201(k) of the act provides that “a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.”

(1) The proprietary name and established name (common or usual name), if any.

(2) The intended use or uses of the product.

(3) For a reagent, a declaration of the established name (common or usual name), if any, and quantity, proportion or concentration of each reactive ingredient; and for a reagent derived from biological material, the source and a measure of its activity. The quantity, proportion, concentration, or activity shall be stated in the system generally used and recognized by the intended user, e.g., metric, international units, etc.

(4) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR Part 1500 and any other warnings appropriate to the hazard presented by the product; and a statement “For In Vitro Diagnostic Use” and any other limiting statements appropriate to the intended use of the product.

(5) For a reagent, appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. For products requiring manipulation, such as reconstitution and/or mixing before use, appropriate storage instructions shall be provided for the reconstituted or mixed product which is to be stored in the

original container. The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in § 211.166 of this chapter.

(6) For a reagent, a means by which the user may be assured that the product meets appropriate standards of identity, strength, quality and purity at the time of use. This shall be provided, both for the product as provided and for any resultant reconstituted or mixed product, by including on the label one or more of the following:

(i) An expiration date based upon the stated storage instructions.

(ii) A statement of an observable indication of an alteration of the product, e.g., turbidity, color change, precipitate, beyond its appropriate standards.

(iii) Instructions for a simple method by which the user can reasonably determine that the product meets its appropriate standards.

(7) For a reagent, a declaration of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package. The use of metric designations is encouraged, wherever appropriate. If more than a single determination may be performed using the product, any statement of the number of tests shall be consistent with instructions for use and amount of material provided.

(8) Name and place of business of manufacturer, packer, or distributor.

(9) A lot or control number, identified as such, from which it is possible to determine the complete manufacturing history of the product.

(i) If it is a multiple unit product, the lot or control number shall permit tracing the identity of the individual units.

(ii) For an instrument, the lot or control number shall permit tracing the identity of all functional subassemblies.

(iii) For multiple unit products which require the use of included units together as a system, all units should bear the same lot or control number, if appropriate, or other suitable uniform identification should be used.

(10) Except that for items in paragraphs (a) (1) through (9) of this section: (i) In the case of immediate containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information and which are packaged within an outer container from which they are removed for use, the information required by paragraphs (a) (2), (3), (4), (5), (6) (ii), (iii) and (7) of this section may appear in the outer container labeling only.

(ii) In any case in which the presence of this information on the immediate container will interfere with the test, the information may appear on the outside container or wrapper rather than on the immediate container label.

(b) Labeling accompanying each product, e.g., a package insert, shall state in one place the following information in the format and order specified below, except where such information is not applicable, or as specified in a standard for a particular product class. The labeling for a multiple-purpose instrument used for diagnostic purposes, and not committed to specific diagnostic procedures or systems, may bear only the information indicated in paragraphs (b) (1), (2), (6), (14), and (15) of this section. The labeling for a reagent intended for use as a replacement in a diagnostic system may be limited to that information necessary to identify the reagent adequately and to describe its proper use in the system.

(1) The proprietary name and established name, i.e., common or usual name, if any.

(2) The intended use or uses of the product and the type of procedure, e.g., qualitative or quantitative.

(3) Summary and explanation of the test. Include a short history of the methodology, with pertinent references and a balanced statement of the special merits and limitations of this method or product. If the product labeling refers to any other procedure, appropriate literature citations shall be included and the labeling shall explain the nature of any differences from the original and their effect on the results.

(4) The chemical, physical, physiological, or biological principles of the procedure. Explain concisely, with

chemical reactions and techniques involved, if applicable.

(5) Reagents: (i) A declaration of the established name (common or usual name), if any, and quantity, proportion or concentration of each reactive ingredient; and for biological material, the source and a measure of its activity. The quantity, proportion, concentration or activity shall be stated in the system generally used and recognized by the intended user, e.g., metric, international units, etc. A statement indicating the presence of and characterizing any catalytic or nonreactive ingredients, e.g., buffers, preservatives, stabilizers.

(ii) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR Part 1500 and any other warnings appropriate to the hazard presented by the product; and a statement "For In Vitro Diagnostic Use" and any other limiting statements appropriate to the intended use of the product.

(iii) Adequate instructions for reconstitution, mixing, dilution, etc.

(iv) Appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. For products requiring manipulation, such as reconstitution and/or mixing before use, appropriate storage instructions shall be provided for the reconstituted or mixed product. The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in §211.166 of this chapter.

(v) A statement of any purification or treatment required for use.

(vi) Physical, biological, or chemical indications of instability or deterioration.

(6) Instruments: (i) Use or function.

(ii) Installation procedures and special requirements.

(iii) Principles of operation.

(iv) Performance characteristics and specifications.

(v) Operating instructions.

(vi) Calibration procedures including materials and/or equipment to be used.

(vii) Operational precautions and limitations.

(viii) Hazards.
(ix) Service and maintenance information.

(7) Specimen collection and preparation for analysis, including a description of: (i) Special precautions regarding specimen collection including special preparation of the patient as it bears on the validity of the test.

(ii) Additives, preservatives, etc., necessary to maintain the integrity of the specimen.

(iii) Known interfering substances.

(iv) Recommended storage, handling or shipping instructions for the protection and maintenance of stability of the specimen.

(8) Procedure: A step-by-step outline of recommended procedures from reception of the specimen to obtaining results. List any points that may be useful in improving precision and accuracy.

(i) A list of all materials provided, e.g., reagents, instruments and equipment, with instructions for their use.

(ii) A list of all materials required but not provided. Include such details as sizes, numbers, types, and quality.

(iii) A description of the amounts of reagents necessary, times required for specific steps, proper temperatures, wavelengths, etc.

(iv) A statement describing the stability of the final reaction material to be measured and the time within which it shall be measured to assure accurate results.

(v) Details of calibration: Identify reference material. Describe preparation of reference sample(s), use of blanks, preparation of the standard curve, etc. The description of the range of calibration should include the highest and the lowest values measurable by the procedure.

(vi) Details of kinds of quality control procedures and materials required. If there is need for both positive and negative controls, this should be stated. State what are considered satisfactory limits of performance.

(9) Results: Explain the procedure for calculating the value of the unknown. Give an explanation for each component of the formula used for the calculation of the unknown. Include a sample calculation, step-by-step, explaining the answer. The values shall

be expressed to the appropriate number of significant figures. If the test provides other than quantitative results, provide an adequate description of expected results.

(10) Limitation of the procedure: Include a statement of limitations of the procedure. State known extrinsic factors or interfering substances affecting results. If further testing, either more specific or more sensitive, is indicated in all cases where certain results are obtained, the need for the additional test shall be stated.

(11) Expected values: State the range(s) of expected values as obtained with the product from studies of various populations. Indicate how the range(s) was established and identify the population(s) on which it was established.

(12) Specific performance characteristics: Include, as appropriate, information describing such things as accuracy, precision, specificity, and sensitivity. These shall be related to a generally accepted method using biological specimens from normal and abnormal populations. Include a statement summarizing the data upon which the specific performance characteristics are based.

(13) Bibliography: Include pertinent references keyed to the text.

(14) Name and place of business of manufacturer, packer, or distributor.

(15) Date of issuance of the last revision of the labeling identified as such.

(c) A shipment or other delivery of an in vitro diagnostic product shall be exempt from the requirements of paragraphs (a) and (b) of this section and from a standard promulgated under part 861 provided that the following conditions are met:

(1) In the case of a shipment or delivery for an investigation subject to part 812, if there has been compliance with part 812; or

(2) In the case of a shipment or delivery for an investigation that is not subject to part 812 (see §812.2(c)), if the following conditions are met:

(i) For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: "For

Research Use Only. Not for use in diagnostic procedures.”

(ii) For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: “For Investigational Use Only. The performance characteristics of this product have not been established.”

(d) The labeling of general purpose laboratory reagents (e.g., hydrochloric acid) and equipment (e.g., test tubes and pipettes) whose uses are generally known by persons trained in their use need not bear the directions for use required by § 809.10 (a) and (b), if their labeling meets the requirements of this paragraph.

(1) The label of a reagent shall bear the following information:

(i) The proprietary name and established name (common or usual name), if any, of the reagent.

(ii) A declaration of the established name (common or usual name), if any, and quantity, proportion or concentration of the reagent ingredient (e.g., hydrochloric acid: Formula weight 36.46, assay 37.9 percent, specific gravity 1.192 at 60 °F); and for a reagent derived from biological material, the source and where applicable a measure of its activity. The quantity, proportion, concentration or activity shall be stated in the system generally used and recognized by the intended user, e.g., metric, international units, etc.

(iii) A statement of the purity and quality of the reagent, including a quantitative declaration of any impurities present. The requirement for this information may be met by a statement of conformity with a generally recognized and generally available standard which contains the same information, e.g., those established by the American Chemical Society, U.S. Pharmacopeia, National Formulary, National Research Council.

(iv) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR Part 1500 and any other warnings appropriate to the hazard presented by the

product; and a statement “For Laboratory Use.”

(v) Appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. The basis for such information shall be determined by reliable, meaningful, and specific test methods such as those described in § 211.166 of this chapter.

(vi) A declaration of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package. The use of metric designations is encouraged, wherever appropriate.

(vii) Name and place of business of manufacturer, packer, or distributor.

(viii) A lot or control number, identified as such, from which it is possible to determine the complete manufacturing history of the product.

(ix) In the case of immediate containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, and which are packaged within an outer container from which they are removed for use, the information required by paragraphs (d)(1)(ii), (iii), (iv), (v), and (vi) of this section may appear in the outer container labeling only.

(2) The label of general purpose laboratory equipment, e.g., a beaker or a pipette, shall bear a statement adequately describing the product, its composition, and physical characteristics if necessary for its proper use.

[41 FR 6903, Feb. 13, 1976, as amended at 45 FR 3750, Jan. 18, 1980; 45 FR 7484, Feb. 1, 1980; 47 FR 41107, Sept. 17, 1982; 47 FR 51109, Nov. 12, 1982; 48 FR 34470, July 29, 1983]

Subpart C—Requirements for Manufacturers and Producers

§ 809.20 General requirements for manufacturers and producers of in vitro diagnostic products.

(a) [Reserved]

(b) *Compliance with good manufacturing practices.* In vitro diagnostic products shall be manufactured in accordance with the good manufacturing

practices requirements found in Part 820 of this chapter.

[41 FR 6903, Feb. 13, 1976, as amended at 42 FR 42530, Aug. 23, 1977; 43 FR 31527, July 21, 1978]

PART 810—MEDICAL DEVICE RECALL AUTHORITY (Eff. 5–19–97)

Subpart A—General Provisions

Sec.

810.1 Scope.

810.2 Definitions.

810.3 Computation of time.

810.4 Service of orders.

Subpart B—Mandatory Medical Device Recall Procedures

810.10 Cease distribution and notification order.

810.11 Regulatory hearing.

810.12 Written request for review of cease distribution and notification order.

810.13 Mandatory recall order.

810.14 Cease distribution and notification or mandatory recall strategy.

810.15 Communications concerning a cease distribution and notification or mandatory recall order.

810.16 Cease distribution and notification or mandatory recall order status reports.

810.17 Termination of a cease distribution and notification or mandatory recall order.

810.18 Public notice.

AUTHORITY: Secs. 201, 301, 302, 303, 304, 501, 502, 518, 701, 704, 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 332, 333, 334, 351, 352, 360h, 371, 374, 375).

SOURCE: 61 FR 59018, Nov. 20, 1996, unless otherwise noted.

EFFECTIVE DATE NOTE: At 61 FR 59018, Nov. 20, 1996, part 810 was added, effective May 19, 1997.

Subpart A—General Provisions

§ 810.1 Scope.

Part 810 describes the procedures that the Food and Drug Administration will follow in exercising its medical device recall authority under section 518(e) of the Federal Food, Drug, and Cosmetic Act.

§ 810.2 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Agency* or *FDA* means the Food and Drug Administration.

(c) *Cease distribution and notification strategy* or *mandatory recall strategy* means a planned, specific course of action to be taken by the person named in a cease distribution and notification order or in a mandatory recall order, which addresses the extent of the notification or recall, the need for public warnings, and the extent of effectiveness checks to be conducted.

(d) *Consignee* means any person or firm that has received, purchased, or used a device that is subject to a cease distribution and notification order or a mandatory recall order. Consignee does not mean lay individuals or patients, i.e., nonhealth professionals.

(e) *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device, without its physical removal from its point of use to some other location.

(f) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment or diagnostic facility that is not a physician's office.

(g) *Health professionals* means practitioners, including physicians, nurses, pharmacists, dentists, respiratory therapists, physical therapists, technologists, or any other practitioners or allied health professionals that have a role in using a device for human use.

(h) *Reasonable probability* means that it is more likely than not that an event will occur.

(i) *Serious, adverse health consequence* means any significant adverse experience, including those that may be either life-threatening or involve permanent or long-term injuries, but excluding injuries that are nonlife-threatening and that are temporary and reasonably reversible.

(j) *Recall* means the correction or removal of a device for human use where FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death.

(k) *Removal* means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

§ 810.3 Computation of time.

In computing any period of time prescribed or allowed by this part, the day of the act or event from which the designated period of time begins to run shall not be included. The computation of time is based only on working days.

§ 810.4 Service of orders.

Orders issued under this part will be served in person by a designated employee of FDA, or by certified or registered mail or similar mail delivery service with a return receipt record reflecting receipt, to the named person or designated agent at the named person's or designated agent's last known address in FDA's records.

Subpart B—Mandatory Medical Device Recall Procedures

§ 810.10 Cease distribution and notification order.

(a) If, after providing the appropriate person with an opportunity to consult with the agency, FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the agency may issue a cease distribution and notification order requiring the person named in the order to immediately:

- (1) Cease distribution of the device;
- (2) Notify health professionals and device user facilities of the order; and
- (3) Instruct these professionals and device user facilities to cease use of the device.

(b) FDA will include the following information in the order:

- (1) The requirements of the order relating to cessation of distribution and notification of health professionals and device user facilities;
- (2) Pertinent descriptive information to enable accurate and immediate identification of the device subject to the order, including, where known:
 - (i) The brand name of the device;
 - (ii) The common name, classification name, or usual name of the device;
 - (iii) The model, catalog, or product code numbers of the device; and
 - (iv) The manufacturing lot numbers or serial numbers of the device or other identification numbers; and

(3) A statement of the grounds for FDA's finding that there is a reasonable probability that the device would cause serious, adverse health consequences or death.

(c) FDA may also include in the order a model letter for notifying health professionals and device user facilities of the order and a requirement that notification of health professionals and device user facilities be completed within a specified timeframe. The model letter will include the key elements of information that the agency in its discretion has determined, based on the circumstances surrounding the issuance of each order, are necessary to inform health professionals and device user facilities about the order.

(d) FDA may also require that the person named in the cease distribution and notification order submit any or all of the following information to the agency by a time specified in the order:

- (1) The total number of units of the device produced and the timespan of the production;
- (2) The total number of units of the device estimated to be in distribution channels;
- (3) The total number of units of the device estimated to be distributed to health professionals and device user facilities;
- (4) The total number of units of the device estimated to be in the hands of home users;
- (5) Distribution information, including the names and addresses of all consignees;
- (6) A copy of any written communication used by the person named in the order to notify health professionals and device user facilities;
- (7) A proposed strategy for complying with the cease distribution and notification order;
- (8) Progress reports to be made at specified intervals, showing the names and addresses of health professionals and device user facilities that have been notified, names of specific individuals contacted within device user facilities, and the dates of such contacts; and
- (9) The name, address, and telephone number of the person who should be contacted concerning implementation of the order.

(e) FDA will provide the person named in a cease distribution and notification order with an opportunity for a regulatory hearing on the actions required by the cease distribution and notification order and on whether the order should be modified, or vacated, or amended to require a mandatory recall of the device.

(f) FDA will also provide the person named in the cease distribution and notification order with an opportunity, in lieu of a regulatory hearing, to submit a written request to FDA asking that the order be modified, or vacated, or amended.

(g) FDA will include in the cease distribution and notification order the name, address, and telephone number of an agency employee to whom any request for a regulatory hearing or agency review is to be addressed.

§ 810.11 Regulatory hearing.

(a) Any request for a regulatory hearing shall be submitted in writing to the agency employee identified in the order within the timeframe specified by FDA. Under § 16.22(b) of this chapter, this timeframe ordinarily will not be fewer than 3 working days after receipt of the cease distribution and notification order. However, as provided in § 16.60(h) of this chapter, the Commissioner of Food and Drugs or presiding officer may waive, suspend, or modify any provision of part 16 under § 10.19 of this chapter, including those pertaining to the timing of the hearing. As provided in § 16.26(a), the Commissioner or presiding officer may deny a request for a hearing, in whole or in part, if he or she determines that no genuine and substantial issue of fact is raised by the material submitted in the request.

(b) If a request for a regulatory hearing is granted, the regulatory hearing shall be limited to:

(1) Reviewing the actions required by the cease distribution and notification order, determining if FDA should affirm, modify, or vacate the order, and addressing an appropriate cease distribution and notification strategy; and

(2) Determining whether FDA should amend the cease distribution and notification order to require a recall of the device that was the subject of the

order. The hearing may also address the actions that might be required by a recall order, including an appropriate recall strategy, if FDA later orders a recall.

(c) If a request by the person named in a cease distribution and notification order for a regulatory hearing is granted, the regulatory hearing will be conducted in accordance with the procedures set out in section 201(x) of the act (21 U.S.C. 321(x)) and part 16 of this chapter, except that the order issued under § 810.10, rather than a notice under § 16.22(a) of this chapter, provides the notice of opportunity for a hearing and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter. As provided in § 16.60(h) of this chapter, the Commissioner of Food and Drugs or presiding officer may waive, suspend, or modify any provision of part 16 under § 10.19 of this chapter. As provided in § 16.26(b), after the hearing commences, the presiding officer may issue a summary decision on any issue if the presiding officer determines that there is no genuine and substantial issue of fact respecting that issue.

(d) If the person named in the cease distribution and notification order does not request a regulatory hearing within the timeframe specified by FDA in the cease distribution and notification order, that person will be deemed to have waived his or her right to request a hearing.

(e) The presiding officer will ordinarily hold any regulatory hearing requested under paragraph (a) of this section no fewer than 2 working days after receipt of the request for a hearing, under § 16.24(e) of this chapter, and no later than 10 working days after the date of issuance of the cease distribution and notification order. However, FDA and the person named in the order may agree to a later date or the presiding officer may determine that the hearing should be held in fewer than 2 days. Moreover, as provided for in § 16.60(h) of this chapter, the Commissioner of Food and Drugs or presiding officer may waive, suspend, or modify any provision of part 16 under § 10.19 of this chapter, including those pertaining to the timing of the hearing. After the presiding officer prepares a written

report of the hearing and the agency issues a final decision based on the report, the presiding officer shall provide the requestor written notification of the final decision to affirm, modify, or vacate the order or to amend the order to require a recall of the device within 15 working days of conducting a regulatory hearing.

§810.12 Written request for review of cease distribution and notification order.

(a) In lieu of requesting a regulatory hearing under §810.11, the person named in a cease distribution and notification order may submit a written request to FDA asking that the order be modified or vacated. Such person shall address the written request to the agency employee identified in the order and shall submit the request within the timeframe specified in the order, unless FDA and the person named in the order agree to a later date.

(b) A written request for review of a cease distribution and notification order shall identify each ground upon which the requestor relies in asking that the order be modified or vacated, as well as addressing an appropriate cease distribution and notification strategy, and shall address whether the order should be amended to require a recall of the device that was the subject of the order and the actions required by such a recall order, including an appropriate recall strategy.

(c) The agency official who issued the cease distribution and notification order shall provide the requestor written notification of the agency's decision to affirm, modify, or vacate the order or amend the order to require a recall of the device within 15 working days of receipt of the written request. The agency official shall include in this written notification:

- (1) A statement of the grounds for the decision to affirm, modify, vacate, or amend the order; and
- (2) The requirements of any modified or amended order.

§810.13 Mandatory recall order.

(a) If the person named in a cease distribution and notification order does not request a regulatory hearing or

submit a request for agency review of the order, or, if the Commissioner of Food and Drugs or the presiding officer denies a request for a hearing, or, if after conducting a regulatory hearing under §810.11 or completing agency review of a cease distribution and notification order under §810.12, FDA determines that the order should be amended to require a recall of the device with respect to which the order was issued, FDA shall amend the order to require such a recall. FDA shall amend the order to require such a recall within 15 working days of issuance of a cease distribution and notification order if a regulatory hearing or agency review of the order is not requested, or within 15 working days of denying a request for a hearing, or within 15 working days of completing a regulatory hearing under §810.11, or within 15 working days of receipt of a written request for review of a cease distribution and notification order under §810.12.

(b) In a mandatory recall order, FDA may:

(1) Specify that the recall is to extend to the wholesale, retail, or user level;

(2) Specify a timetable in accordance with which the recall is to begin and be completed;

(3) Require the person named in the order to submit to the agency a proposed recall strategy, as described in §810.14, and periodic reports describing the progress of the mandatory recall, as described in §810.16; and

(4) Provide the person named in the order with a model recall notification letter that includes the key elements of information that FDA has determined are necessary to inform health professionals and device user facilities.

(c) FDA will not include in a mandatory recall order a requirement for:

(1) Recall of a device from individuals; or

(2) Recall of a device from device user facilities, if FDA determines that the risk of recalling the device from the facilities presents a greater health risk than the health risk of not recalling the device from use, unless the device can be replaced immediately with an equivalent device.

(d) FDA will include in a mandatory recall order provisions for notification

to individuals subject to the risks associated with use of the device. If a significant number of such individuals cannot be identified, FDA may notify such individuals under section 705(b) of the act.

§ 810.14 Cease distribution and notification or mandatory recall strategy.

(a) *General.* The person named in a cease distribution and notification order issued under § 810.10 shall comply with the order, which FDA will fashion as appropriate for the individual circumstances of the case. The person named in a cease distribution and notification order modified under § 810.11(e) or § 810.12(c) or a mandatory recall order issued under § 810.13 shall develop a strategy for complying with the order that is appropriate for the individual circumstances and that takes into account the following factors:

(1) The nature of the serious, adverse health consequences related to the device;

(2) The ease of identifying the device;

(3) The extent to which the risk presented by the device is obvious to a health professional or device user facility; and

(4) The extent to which the device is used by health professionals and device user facilities.

(b) *Submission and review.* (1) The person named in the cease distribution and notification order modified under § 810.11(e) or § 810.12(c) or mandatory recall order shall submit a copy of the proposed strategy to the agency within the timeframe specified in the order.

(2) The agency will review the proposed strategy and make any changes to the strategy that it deems necessary within 7 working days of receipt of the proposed strategy. The person named in the order shall act in accordance with a strategy determined by FDA to be appropriate.

(c) *Elements of the strategy.* A proposed strategy shall meet all of the following requirements:

(1)(i) The person named in the order shall specify the level in the chain of distribution to which the cease distribution and notification order or mandatory recall order is to extend as follows:

(A) Consumer or user level, e.g., health professionals, consignee, or device user facility level, including any intermediate wholesale or retail level; or

(B) Retail level, to the level immediately preceding the consumer or user level, and including any intermediate level; or

(C) Wholesale level.

(ii) The person named in the order shall not recall a device from individuals; and

(iii) The person named in the order shall not recall a device from device user facilities if FDA notifies the person not to do so because of a risk determination under § 810.13(c)(2).

(2) The person named in a recall order shall ensure that the strategy provides for notice to individuals subject to the risks associated with use of the recalled device. The notice may be provided through the individuals' health professionals if FDA determines that such consultation is appropriate and would be the most effective method of notifying patients.

(3) Effectiveness checks by the person named in the order are required to verify that all health professionals, device user facilities, consignees, and individuals, as appropriate, have been notified of the cease distribution and notification order or mandatory recall order and of the need to take appropriate action. The person named in the cease distribution and notification order or the mandatory recall order shall specify in the strategy the method(s) to be used in addition to written communications as required by § 810.15, i.e., personal visits, telephone calls, or a combination thereof to contact all health professionals, device user facilities, consignees, and individuals, as appropriate. The agency may conduct additional audit checks where appropriate.

§ 810.15 Communications concerning a cease distribution and notification or mandatory recall order.

(a) *General.* The person named in a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 is responsible for promptly notifying each health professional, device user

facility, consignee, or individual, as appropriate, of the order. In accordance with § 810.10(c) or § 810.13(b)(4), FDA may provide the person named in the cease distribution and notification or mandatory recall order with a model letter for notifying each health professional, device user facility, consignee, or individual, as appropriate, of the order. However, if FDA does not provide the person named in the cease distribution and notification or mandatory recall order with a model letter, the person named in a cease distribution and notification order issued under § 810.10, or a mandatory recall order issued under § 810.13, is responsible for providing such notification. The purpose of the communication is to convey:

(1) That FDA has found that there is a reasonable probability that use of the device would cause a serious, adverse health consequence or death;

(2) That the person named in the order has ceased distribution of the device;

(3) That health professionals and device user facilities should cease use of the device immediately;

(4) Where appropriate, that the device is subject to a mandatory recall order; and

(5) Specific instructions on what should be done with the device.

(b) *Implementation.* The person named in a cease distribution and notification order, or a mandatory recall order, shall notify the appropriate person(s) of the order by verified written communication, e.g., telegram, mailgram, or fax. The written communication and any envelope in which it is sent or enclosed shall be conspicuously marked, preferably in bold red ink: "URGENT—[DEVICE CEASE DISTRIBUTION AND NOTIFICATION ORDER] or [MANDATORY DEVICE RECALL ORDER]." Telephone calls or other personal contacts may be made in addition to, but not as a substitute for, the verified written communication, and shall be documented in an appropriate manner.

(c) *Contents.* The person named in the order shall ensure that the notice of a cease distribution and notification order or mandatory recall order:

(1) Is brief and to the point;

(2) Identifies clearly the device, size, lot number(s), code(s), or serial number(s), and any other pertinent descriptive information to facilitate accurate and immediate identification of the device;

(3) Explains concisely the serious, adverse health consequences that may occur if use of the device were continued;

(4) Provides specific instructions on what should be done with the device;

(5) Provides a ready means for the recipient of the communication to confirm receipt of the communication and to notify the person named in the order of the actions taken in response to the communication. Such means may include, but are not limited to, the return of a postage-paid, self-addressed post card or a toll-free call to the person named in the order; and

(6) Does not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message.

(d) *Followup communications.* The person named in the cease distribution and notification order or mandatory recall order shall ensure that followup communications are sent to all who fail to respond to the initial communication.

(e) *Responsibility of the recipient.* Health professionals, device user facilities, and consignees who receive a communication concerning a cease distribution and notification order or a mandatory recall order should immediately follow the instructions set forth in the communication. Where appropriate, these recipients should immediately notify their consignees of the order in accordance with paragraphs (b) and (c) of this section.

§ 810.16 Cease distribution and notification or mandatory recall order status reports.

(a) The person named in a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 shall submit periodic status reports to FDA to enable the agency to assess the person's progress in complying with the order. The frequency of such reports and the agency official to whom such reports

shall be submitted will be specified in the order.

(b) Unless otherwise specified in the order, each status report shall contain the following information:

(1) The number and type of health professionals, device user facilities, consignees, or individuals notified about the order and the date and method of notification;

(2) The number and type of health professionals, device user facilities, consignees, or individuals who have responded to the communication and the quantity of the device on hand at these locations at the time they received the communication;

(3) The number and type of health professionals, device user facilities, consignees, or individuals who have not responded to the communication;

(4) The number of devices returned or corrected by each health professional, device user facility, consignee, or individual contacted, and the quantity of products accounted for;

(5) The number and results of effectiveness checks that have been made; and

(6) Estimated timeframes for completion of the requirements of the cease distribution and notification order or mandatory recall order.

(c) The person named in the cease distribution and notification order or recall order may discontinue the submission of status reports when the agency terminates the order in accordance with § 810.17.

§ 810.17 Termination of a cease distribution and notification or mandatory recall order.

(a) The person named in a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 may request termination of the order by submitting a written request to FDA. The person submitting a request shall certify that he or she has complied in full with all of the requirements of the order and shall include a copy of the most current status report submitted to the agency under § 810.16. A request for termination of a recall order shall include a description of the disposition of the recalled device.

(b) FDA may terminate a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 when the agency determines that the person named in the order:

(1) Has taken all reasonable efforts to ensure and to verify that all health professionals, device user facilities, consignees, and, where appropriate, individuals have been notified of the cease distribution and notification order, and to verify that they have been instructed to cease use of the device and to take other appropriate action; or

(2) Has removed the device from the market or has corrected the device so that use of the device would not cause serious, adverse health consequences or death.

(c) FDA will provide written notification to the person named in the order when a request for termination of a cease distribution and notification order or a mandatory recall order has been granted or denied. FDA will respond to a written request for termination of a cease distribution and notification or recall order within 30 working days of its receipt.

§ 810.18 Public notice.

The agency will make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new mandatory recall issued under § 810.13. The agency will delay public notification of orders when the agency determines that such notification may cause unnecessary and harmful anxiety in individuals and that initial consultation between individuals and their health professionals is essential.

**PART 812—INVESTIGATIONAL
DEVICE EXEMPTIONS**

Subpart A—General Provisions

Sec.

812.1 Scope.

812.2 Applicability.

812.3 Definitions.

812.5 Labeling of investigational devices.

812.7 Prohibition of promotion and other practices.

812.10 Waivers.

812.18 Import and export requirements.

Food and Drug Administration, HHS

§ 812.1

812.19 Address for IDE correspondence.

Subpart B—Application and Administrative Action

812.20 Application.
812.25 Investigational plan.
812.27 Report of prior investigations.
812.30 FDA action on applications.
812.35 Supplemental applications.
812.38 Confidentiality of data and information.

Subpart C—Responsibilities of Sponsors

812.40 General responsibilities of sponsors.
812.42 FDA and IRB approval.
812.43 Selecting investigators and monitors.
812.45 Informing investigators.
812.46 Monitoring investigations.
812.47 Emergency research under § 50.24 of this chapter.

Subpart D—IRB Review and Approval

812.60 IRB composition, duties, and functions.
812.62 IRB approval.
812.64 IRB's continuing review.
812.65 [Reserved]
812.66 Significant risk device determinations.

Subpart E—Responsibilities of Investigators

812.100 General responsibilities of investigators.
812.110 Specific responsibilities of investigators.
812.119 Disqualification of a clinical investigator.

Subpart F [Reserved]

Subpart G—Records and Reports

812.140 Records.
812.145 Inspections.
812.150 Reports.

AUTHORITY: Secs. 301, 501, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 702, 704, 721, 801, 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 383); secs. 215, 301, 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b–263n).

SOURCE: 45 FR 3751, Jan. 18, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 812.1 Scope.

(a) The purpose of this part is to encourage, to the extent consistent with the protection of public health and

safety and with ethical standards, the discovery and development of useful devices intended for human use, and to that end to maintain optimum freedom for scientific investigators in their pursuit of this purpose. This part provides procedures for the conduct of clinical investigations of devices. An approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device. An IDE approved under § 812.30 or considered approved under § 812.2(b) exempts a device from the requirements of the following sections of the Federal Food, Drug, and Cosmetic Act (the act) and regulations issued thereunder: Misbranding under section 502 of the act, registration, listing, and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, a banned device regulation under section 516, records and reports under section 519, restricted device requirements under section 520(e), good manufacturing practice requirements under section 520(f) except for the requirements found in § 820.30, if applicable (unless the sponsor states an intention to comply with these requirements under § 812.20(b)(3) or § 812.140(b)(4)(v)) and color additive requirements under section 721.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[45 FR 3751, Jan. 18, 1980, as amended at 59 FR 14366, Mar. 28, 1994; 61 FR 52654, Oct. 7, 1996]

EFFECTIVE DATE NOTE: At 61 FR 52654, Oct. 7, 1996, § 812.1 was amended by revising the fourth sentence of paragraph (a), effective June 1, 1997. For the convenience of the user, the superseded text is set forth as follows:

§ 812.1 Scope.

(a) * * * An IDE approved under § 812.30 or considered approved under § 812.2(b) exempts a device from the requirements of the following sections of the act and regulations issued thereunder: Misbranding under section 502, registration, listing, and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, a banned device regulation

under section 516, records and reports under section 519, restricted device requirements under section 520(e), good manufacturing practice requirements under section 520(f) (unless the sponsor states an intention to comply with these requirements under § 812.20(b)(3) or § 812.140(b)(4)(v)) and color additive requirements under section 721.

* * * * *

§ 812.2 Applicability.

(a) *General.* This part applies to all clinical investigations of devices to determine safety and effectiveness, except as provided in paragraph (c) of this section.

(b) *Abbreviated requirements.* The following categories of investigations are considered to have approved applications for IDE's, unless FDA has notified a sponsor under § 812.20(a) that approval of an application is required:

(1) An investigation of a device other than a significant risk device, if the device is not a banned device and the sponsor:

(i) Labels the device in accordance with § 812.5;

(ii) Obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval;

(iii) Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent under Part 50 and documents it, unless documentation is waived by an IRB under § 56.109(c).

(iv) Complies with the requirements of § 812.46 with respect to monitoring investigations;

(v) Maintains the records required under § 812.140(b) (4) and (5) and makes the reports required under § 812.150(b) (1) through (3) and (5) through (10);

(vi) Ensures that participating investigators maintain the records required by § 812.140(a)(3)(i) and make the reports required under § 812.150(a) (1), (2), (5), and (7); and

(vii) Complies with the prohibitions in § 812.7 against promotion and other practices.

(2) An investigation of a device other than one subject to paragraph (e) of this section, if the investigation was begun on or before July 16, 1980, and to

be completed, and is completed, on or before January 19, 1981.

(c) *Exempted investigations.* This part, with the exception of § 812.119, does not apply to investigations of the following categories of devices:

(1) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

(2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under Subpart E of Part 807 in determining substantial equivalence.

(3) A diagnostic device, if the sponsor complies with applicable requirements in § 809.10(c) and if the testing:

(i) Is noninvasive,

(ii) Does not require an invasive sampling procedure that presents significant risk,

(iii) Does not by design or intention introduce energy into a subject, and

(iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

(4) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

(5) A device intended solely for veterinary use.

(6) A device shipped solely for research on or with laboratory animals and labeled in accordance with § 812.5(c).

(7) A custom device as defined in § 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

(d) *Limit on certain exemptions.* In the case of class II or class III device described in paragraph (c)(1) or (2) of this section, this part applies beginning on

the date stipulated in an FDA regulation or order that calls for the submission of premarket approval applications for an unapproved class III device, or establishes a performance standard for a class II device.

(e) *Investigations subject to IND's.* A sponsor that, on July 16, 1980, has an effective investigational new drug application (IND) for an investigation of a device shall continue to comply with the requirements of Part 312 until 90 days after that date. To continue the investigation after that date, a sponsor shall comply with paragraph (b)(1) of this section, if the device is not a significant risk device, or shall have obtained FDA approval under § 812.30 of an IDE application for the investigation of the device.

[45 FR 3751, Jan. 18, 1980, as amended at 46 FR 8956, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981; 53 FR 11252, Apr. 6, 1988; 62 FR 4165, Jan. 29, 1997; 62 FR 12096, Mar. 14, 1997]

EFFECTIVE DATE NOTE: At 62 FR 12096, Mar. 14, 1997, § 812.2 was amended by revising the introductory text of paragraph (c), effective May 13, 1997. For the convenience of the user, the superseded text is set forth as follows:

§ 812.2 Applicability.

* * * * *

(c) *Exempted investigations.* This part does not apply to investigations of the following categories of devices:

* * * * *

§ 812.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act (sections 201-901, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 301-392)).

(b) *Custom device* means a device that:

(1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;

(2) Is not generally available to, or generally used by, other physicians or dentists;

(3) Is not generally available in finished form for purchase or for dispensing upon prescription;

(4) Is not offered for commercial distribution through labeling or advertising; and

(5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

(c) *FDA* means the Food and Drug Administration.

(d) *Implant* means a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also "implants" for purposes of this part.

(e) *Institution* means a person, other than an individual, who engages in the conduct of research on subjects or in the delivery of medical services to individuals as a primary activity or as an adjunct to providing residential or custodial care to humans. The term includes, for example, a hospital, retirement home, confinement facility, academic establishment, and device manufacturer. The term has the same meaning as "facility" in section 520(g) of the act.

(f) *Institutional review board* (IRB) means any board, committee, or other group formally designated by an institution to review biomedical research involving subjects and established, operated, and functioning in conformance with part 56. The term has the same meaning as "institutional review committee" in section 520(g) of the act.

(g) *Investigational device* means a device, including a transitional device, that is the object of an investigation.

(h) *Investigation* means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

(i) *Investigator* means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(j) *Monitor*, when used as a noun, means an individual designated by a sponsor or contract research organization to oversee the progress of an investigation. The monitor may be an employee of a sponsor or a consultant to the sponsor, or an employee of or consultant to a contract research organization. *Monitor*, when used as a verb, means to oversee an investigation.

(k) *Noninvasive*, when applied to a diagnostic device or procedure, means one that does not by design or intention: (1) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or (2) enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os. For purposes of this part, blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for noninvestigational purposes is also considered noninvasive.

(l) *Person* includes any individual, partnership, corporation, association, scientific or academic establishment, Government agency or organizational unit of a Government agency, and any other legal entity.

(m) *Significant risk device* means an investigational device that:

(1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

(2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;

(3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

(4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

(n) *Sponsor* means a person who initiates, but who does not actually conduct, the investigation, that is, the investigational device is administered, dispensed, or used under the immediate

direction of another individual. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

(o) *Sponsor-investigator* means an individual who both initiates and actually conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other than an individual. The obligations of a sponsor-investigator under this part include those of an investigator and those of a sponsor.

(p) *Subject* means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.

(q) *Termination* means a discontinuance, by sponsor or by withdrawal of IRB or FDA approval, of an investigation before completion.

(r) *Transitional device* means a device subject to section 520(l) of the act, that is, a device that FDA considered to be a new drug or an antibiotic drug before May 28, 1976.

(s) *Unanticipated adverse device effect* means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

[45 FR 3751, Jan. 18, 1980, as amended at 46 FR 8956, Jan. 27, 1981; 48 FR 15622, Apr. 12, 1983]

§ 812.5 Labeling of investigational devices.

(a) *Contents*. An investigational device or its immediate package shall bear a label with the following information: the name and place of business of the manufacturer, packer, or distributor (in accordance with § 801.1),

the quantity of contents, if appropriate, and the following statement: "CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use." The label or other labeling shall describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.

(b) *Prohibitions.* The labeling of an investigational device shall not bear any statement that is false or misleading in any particular and shall not represent that the device is safe or effective for the purposes for which it is being investigated.

(c) *Animal research.* An investigational device shipped solely for research on or with laboratory animals shall bear on its label the following statement: "CAUTION—Device for investigational use in laboratory animals or other tests that do not involve human subjects."

[45 FR 3751, Jan. 18, 1980, as amended at 45 FR 58842, Sept. 5, 1980]

§ 812.7 Prohibition of promotion and other practices.

A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:

(a) Promote or test market an investigational device, until after FDA has approved the device for commercial distribution.

(b) Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling.

(c) Unduly prolong an investigation. If data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified or in the case of a class II device that it will not comply with an applicable performance standard or an amendment to that standard, the sponsor shall promptly terminate the investigation.

(d) Represent that an investigational device is safe or effective for the purposes for which it is being investigated.

§ 812.10 Waivers.

(a) *Request.* A sponsor may request FDA to waive any requirement of this part. A waiver request, with supporting documentation, may be submitted separately or as part of an application to the address in § 812.19.

(b) *FDA action.* FDA may by letter grant a waiver of any requirement that FDA finds is not required by the act and is unnecessary to protect the rights, safety, or welfare of human subjects.

(c) *Effect of request.* Any requirement shall continue to apply unless and until FDA waives it.

§ 812.18 Import and export requirements.

(a) *Imports.* In addition to complying with other requirements of this part, a person who imports or offers for importation an investigational device subject to this part shall be the agent of the foreign exporter with respect to investigations of the device and shall act as the sponsor of the clinical investigation, or ensure that another person acts as the agent of the foreign exporter and the sponsor of the investigation.

(b) *Exports.* A person exporting an investigational device subject to this part shall obtain FDA's prior approval, as required by section 801(d) of the act.

§ 812.19 Address for IDE correspondence.

All applications, supplemental applications, reports, requests for waivers, requests for import or export approval, and other correspondence relating to matters covered by this part shall be addressed to the Center for Devices and Radiological Health, Document Mail Center (HFZ-401), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850. The outside wrapper of each submission shall state what the submission is, for example an "IDE application," a "supplemental IDE application," or "correspondence concerning an IDE (or an IDE application)."

[45 FR 3751, Jan. 18, 1980, as amended at 53 FR 11252, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

Subpart B—Application and Administrative Action

§ 812.20 Application.

(a) *Submission.* (1) A sponsor shall submit an application to FDA if the sponsor intends to use a significant risk device in an investigation, intends to conduct an investigation that involves an exception from informed consent under § 50.24 of this chapter, or if FDA notifies the sponsor that an application is required for an investigation.

(2) A sponsor shall not begin an investigation for which FDA's approval of an application is required until FDA has approved the application.

(3) A sponsor shall submit three copies of a signed "Application for an Investigational Device Exemption" (IDE application), together with accompanying materials, by registered mail or by hand to the address in § 812.19. Subsequent correspondence concerning an application or a supplemental application shall be submitted by registered mail or by hand.

(4)(i) A sponsor shall submit a separate IDE for any clinical investigation involving an exception from informed consent under § 50.24 of this chapter. Such a clinical investigation is not permitted to proceed without the prior written authorization of FDA. FDA shall provide such written authorization 30 days after FDA receives the IDE or earlier.

(ii) If the investigation involves an exception from informed consent under § 50.24 of this chapter, the sponsor shall prominently identify on the cover sheet that the investigation is subject to the requirements in § 50.24 of this chapter.

(b) *Contents.* An IDE application shall include, in the following order:

(1) The name and address of the sponsor.

(2) A complete report of prior investigations of the device and an accurate summary of those sections of the investigational plan described in § 812.25(a) through (e) or, in lieu of the summary, the complete plan. The sponsor shall submit to FDA a complete investigational plan and a complete report of prior investigations of the device if no IRB has reviewed them, if FDA has

found an IRB's review inadequate, or if FDA requests them.

(3) A description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device.

(4) An example of the agreements to be entered into by all investigators to comply with investigator obligations under this part, and a list of the names and addresses of all investigators who have signed the agreement.

(5) A certification that all investigators who will participate in the investigation have signed the agreement, that the list of investigators includes all the investigators participating in the investigation, and that no investigators will be added to the investigation until they have signed the agreement.

(6) A list of the name, address, and chairperson of each IRB that has been or will be asked to review the investigation and a certification of the action concerning the investigation taken by each such IRB.

(7) The name and address of any institution at which a part of the investigation may be conducted that has not been identified in accordance with paragraph (b)(6) of this section.

(8) If the device is to be sold, the amount to be charged and an explanation of why sale does not constitute commercialization of the device.

(9) A claim for categorical exclusion under § 25.24 or an environmental assessment under § 25.31.

(10) Copies of all labeling for the device.

(11) Copies of all forms and informational materials to be provided to subjects to obtain informed consent.

(12) Any other relevant information FDA requests for review of the application.

(c) *Additional information.* FDA may request additional information concerning an investigation or revision in the investigational plan. The sponsor

may treat such a request as a disapproval of the application for purposes of requesting a hearing under Part 16.

(d) *Information previously submitted.* Information previously submitted to the Center for Devices and Radiological Health in accordance with this chapter ordinarily need not be resubmitted, but may be incorporated by reference.

[45 FR 3751, Jan. 18, 1980, as amended at 46 FR 8956, Jan. 27, 1981; 50 FR 16669, Apr. 26, 1985; 53 FR 11252, Apr. 6, 1988; 61 FR 51530, Oct. 2, 1996]

§ 812.25 Investigational plan.

The investigational plan shall include, in the following order:

(a) *Purpose.* The name and intended use of the device and the objectives and duration of the investigation.

(b) *Protocol.* A written protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound.

(c) *Risk analysis.* A description and analysis of all increased risks to which subjects will be exposed by the investigation; the manner in which these risks will be minimized; a justification for the investigation; and a description of the patient population, including the number, age, sex, and condition.

(d) *Description of device.* A description of each important component, ingredient, property, and principle of operation of the device and of each anticipated change in the device during the course of the investigation.

(e) *Monitoring procedures.* The sponsor's written procedures for monitoring the investigation and the name and address of any monitor.

(f) *Labeling.* Copies of all labeling for the device.

(g) *Consent materials.* Copies of all forms and informational materials to be provided to subjects to obtain informed consent.

(h) *IRB information.* A list of the names, locations, and chairpersons of all IRB's that have been or will be asked to review the investigation, and a certification of any action taken by any of those IRB's with respect to the investigation.

(i) *Other institutions.* The name and address of each institution at which a part of the investigation may be conducted that has not been identified in paragraph (h) of this section.

(j) *Additional records and reports.* A description of records and reports that will be maintained on the investigation in addition to those prescribed in Subpart G.

§ 812.27 Report of prior investigations.

(a) *General.* The report of prior investigations shall include reports of all prior clinical, animal, and laboratory testing of the device and shall be comprehensive and adequate to justify the proposed investigation.

(b) *Specific contents.* The report also shall include:

(1) A bibliography of all publications, whether adverse or supportive, that are relevant to an evaluation of the safety or effectiveness of the device, copies of all published and unpublished adverse information, and, if requested by an IRB or FDA, copies of other significant publications.

(2) A summary of all other unpublished information (whether adverse or supportive) in the possession of, or reasonably obtainable by, the sponsor that is relevant to an evaluation of the safety or effectiveness of the device.

(3) If information on nonclinical laboratory studies is provided, a statement that all such studies have been conducted in compliance with applicable requirements in the good laboratory practice regulations in Part 58, or if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with this requirement does not justify failure to provide information on a relevant nonclinical test study.

[45 FR 3751, Jan. 18, 1980, as amended at 50 FR 7518, Feb. 22, 1985]

§ 812.30 FDA action on applications.

(a) *Approval or disapproval.* FDA will notify the sponsor in writing of the date it receives an application. FDA may approve an investigation as proposed, approve it with modifications, or disapprove it. An investigation may not begin until:

(1) Thirty days after FDA receives the application at the address in §812.19 for the investigation of a device other than a banned device, unless FDA notifies the sponsor that the investigation may not begin; or

(2) FDA approves, by order, an IDE for the investigation.

(b) *Grounds for disapproval or withdrawal.* FDA may disapprove or withdraw approval of an application if FDA finds that:

(1) There has been a failure to comply with any requirement of this part or the act, any other applicable regulation or statute, or any condition of approval imposed by an IRB or FDA.

(2) The application or a report contains an untrue statement of a material fact, or omits material information required by this part.

(3) The sponsor fails to respond to a request for additional information within the time prescribed by FDA.

(4) There is reason to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective.

(5) It is otherwise unreasonable to begin or to continue the investigation owing to the way in which the device is used or the inadequacy of:

(i) The report of prior investigations or the investigational plan;

(ii) The methods, facilities, and controls used for the manufacturing, processing, packaging, storage, and, where appropriate, installation of the device; or

(iii) Monitoring and review of the investigation.

(c) *Notice of disapproval or withdrawal.* If FDA disapproves an application or proposes to withdraw approval of an application, FDA will notify the sponsor in writing.

(1) A disapproval order will contain a complete statement of the reasons for disapproval and a statement that the sponsor has an opportunity to request a hearing under Part 16.

(2) A notice of a proposed withdrawal of approval will contain a complete statement of the reasons for with-

drawal and a statement that the sponsor has an opportunity to request a hearing under Part 16. FDA will provide the opportunity for hearing before withdrawal of approval, unless FDA determines in the notice that continuation of testing under the exemption will result in an unreasonable risk to the public health and orders withdrawal of approval before any hearing.

[45 FR 3751, Jan. 18, 1980, as amended at 45 FR 58842, Sept. 5, 1980]

§812.35 Supplemental applications.

(a) *Changes in investigational plan.* A sponsor shall: (1) Submit to FDA a supplemental application if the sponsor or an investigator proposes a change in the investigational plan that may affect its scientific soundness or the rights, safety, or welfare of subjects, and (2) obtain FDA approval under §812.30(a) of any such change, and IRB approval when the change involves the rights, safety, or welfare of subjects (see §§56.110 and 56.111), before implementation. These requirements do not apply in the case of a deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency, which deviation shall be reported to FDA within 5 working days after the sponsor learns of it (see §812.150(a)(4)). Whenever a sponsor intends to conduct a clinical investigation with an exception from informed consent for emergency research as set forth in §50.24 of this chapter, the sponsor shall submit a separate IDE for such investigation.

(b) *IRB approval for new facilities.* A sponsor shall submit to FDA a certification of any IRB approval of an investigation or a part of an investigation not included in the IDE application. If the investigation is otherwise unchanged, the supplemental application shall consist of an updating of the information required by §812.20(b) and (c) and a description of any modifications in the investigational plan required by the IRB as a condition of approval. A certification of IRB approval need not be included in the initial submission of the supplemental application, and such certification is not a precondition for agency consideration of the application. Nevertheless, a sponsor may not

begin a part of an investigation at a facility until the IRB has approved the investigation, FDA has received the certification of IRB approval, and FDA, under § 812.30(a), has approved the supplemental application relating to that part of the investigation (see § 56.103(a)).

[50 FR 25909, June 24, 1985; 50 FR 28932, July 17, 1985; 61 FR 51531, Oct. 2, 1996]

§ 812.38 Confidentiality of data and information.

(a) *Existence of IDE.* FDA will not disclose the existence of an IDE unless its existence has previously been publicly disclosed or acknowledged, until FDA approves an application for premarket approval of the device subject to the IDE; or a notice of completion of a product development protocol for the device has become effective.

(b) *Availability of summaries or data.* (1) FDA will make publicly available, upon request, a detailed summary of information concerning the safety and effectiveness of the device that was the basis for an order approving, disapproving, or withdrawing approval of an application for an IDE for a banned device. The summary shall include information on any adverse effect on health caused by the device.

(2) If a device is a banned device or if the existence of an IDE has been publicly disclosed or acknowledged, data or information contained in the file is not available for public disclosure before approval of an application for premarket approval or the effective date of a notice of completion of a product development protocol except as provided in this section. FDA may, in its discretion, disclose a summary of selected portions of the safety and effectiveness data, that is, clinical, animal, or laboratory studies and tests of the device, for public consideration of a specific pending issue.

(3) If the existence of an IDE file has not been publicly disclosed or acknowledged, no data or information in the file are available for public disclosure except as provided in paragraphs (b)(1) and (c) of this section.

(4) Notwithstanding paragraph (b)(2) of this section, FDA will make available to the public, upon request, the information in the IDE that was required

to be filed in Docket Number 95S-0158 in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, for investigations involving an exception from informed consent under § 50.24 of this chapter. Persons wishing to request this information shall submit a request under the Freedom of Information Act.

(c) *Reports of adverse effects.* Upon request or on its own initiative, FDA shall disclose to an individual on whom an investigational device has been used a copy of a report of adverse device effects relating to that use.

(d) *Other rules.* Except as otherwise provided in this section, the availability for public disclosure of data and information in an IDE file shall be handled in accordance with § 814.9.

[45 FR 3751, Jan. 18, 1980, as amended at 53 FR 11253, Apr. 6, 1988; 61 FR 51531, Oct. 2, 1996]

Subpart C—Responsibilities of Sponsors

§ 812.40 General responsibilities of sponsors.

Sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that IRB review and approval are obtained, submitting an IDE application to FDA, and ensuring that any reviewing IRB and FDA are promptly informed of significant new information about an investigation. Additional responsibilities of sponsors are described in Subparts B and G.

§ 812.42 FDA and IRB approval.

A sponsor shall not begin an investigation or part of an investigation until an IRB and FDA have both approved the application or supplemental application relating to the investigation or part of an investigation.

[46 FR 8957, Jan. 27, 1981]

§ 812.43 Selecting investigators and monitors.

(a) *Selecting investigators.* A sponsor shall select investigators qualified by

training and experience to investigate the device.

(b) *Control of device.* A sponsor shall ship investigational devices only to qualified investigators participating in the investigation.

(c) *Obtaining agreements.* A sponsor shall obtain from each participating investigator a signed agreement that includes:

(1) The investigator's curriculum vitae.

(2) Where applicable, a statement of the investigator's relevant experience, including the dates, location, extent, and type of experience.

(3) If the investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to termination.

(4) A statement of the investigator's commitment to:

(i) Conduct the investigation in accordance with the agreement, the investigational plan, this part and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB or FDA;

(ii) Supervise all testing of the device involving human subjects; and

(iii) Ensure that the requirements for obtaining informed consent are met.

(d) *Selecting monitors.* A sponsor shall select monitors qualified by training and experience to monitor the investigational study in accordance with this part and other applicable FDA regulations.

§ 812.45 Informing investigators.

A sponsor shall supply all investigators participating in the investigation with copies of the investigational plan and the report of prior investigations of the device.

§ 812.46 Monitoring investigations.

(a) *Securing compliance.* A sponsor who discovers that an investigator is not complying with the signed agreement, the investigational plan, the requirements of this part or other applicable FDA regulations, or any conditions of approval imposed by the reviewing IRB or FDA shall promptly either secure compliance, or discontinue shipments of the device to the investigator and terminate the investigator's participation in the investigation.

A sponsor shall also require such an investigator to dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject.

(b) *Unanticipated adverse device effects.*

(1) A sponsor shall immediately conduct an evaluation of any unanticipated adverse device effect.

(2) A sponsor who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects shall terminate all investigations or parts of investigations presenting that risk as soon as possible. Termination shall occur not later than 5 working days after the sponsor makes this determination and not later than 15 working days after the sponsor first received notice of the effect.

(c) *Resumption of terminated studies.* If the device is a significant risk device, a sponsor may not resume a terminated investigation without IRB and FDA approval. If the device is not a significant risk device, a sponsor may not resume a terminated investigation without IRB approval and, if the investigation was terminated under paragraph (b)(2) of this section, FDA approval.

§ 812.47 Emergency research under § 50.24 of this chapter.

(a) The sponsor shall monitor the progress of all investigations involving an exception from informed consent under § 50.24 of this chapter. When the sponsor receives from the IRB information concerning the public disclosures under § 50.24(a)(7)(ii) and (a)(7)(iii) of this chapter, the sponsor shall promptly submit to the IDE file and to Docket Number 95S-0158 in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, copies of the information that was disclosed, identified by the IDE number.

(b) The sponsor also shall monitor such investigations to determine when an IRB determines that it cannot approve the research because it does not meet the criteria in the exception in § 50.24(a) of this chapter or because of other relevant ethical concerns. The sponsor promptly shall provide this information in writing to FDA investigators who are asked to participate in

this or a substantially equivalent clinical investigation and other IRB's that are asked to review this or a substantially equivalent investigation.

[61 FR 51531, Oct. 2, 1996]

Subpart D—IRB Review and Approval

§ 812.60 IRB composition, duties, and functions.

An IRB reviewing and approving investigations under this part shall comply with the requirements of Part 56 in all respects, including its composition, duties, and functions.

[46 FR 8957, Jan. 27, 1981]

§ 812.62 IRB approval.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all investigations covered by this part.

(b) If no IRB exists or if FDA finds that an IRB's review is inadequate, a sponsor may submit an application to FDA.

[46 FR 8957, Jan. 27, 1981]

§ 812.64 IRB's continuing review.

The IRB shall conduct its continuing review of an investigation in accordance with Part 56.

[46 FR 8957, Jan. 27, 1981]

§ 812.65 [Reserved]

§ 812.66 Significant risk device determinations.

If an IRB determines that an investigation, presented for approval under § 812.2(b)(1)(ii), involves a significant risk device, it shall so notify the investigator and, where appropriate, the sponsor. A sponsor may not begin the investigation except as provided in § 812.30(a).

[46 FR 8957, Jan. 27, 1981]

Subpart E—Responsibilities of Investigators

§ 812.100 General responsibilities of investigators.

An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with Part 50 of this chapter. Additional responsibilities of investigators are described in Subpart G.

[45 FR 3751, Jan. 18, 1980, as amended at 46 FR 8957, Jan. 27, 1981]

§ 812.110 Specific responsibilities of investigators.

(a) *Awaiting approval.* An investigator may determine whether potential subjects would be interested in participating in an investigation, but shall not request the written informed consent of any subject to participate, and shall not allow any subject to participate before obtaining IRB and FDA approval.

(b) *Compliance.* An investigator shall conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, this part and other applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA.

(c) *Supervising device use.* An investigator shall permit an investigational device to be used only with subjects under the investigator's supervision. An investigator shall not supply an investigational device to any person not authorized under this part to receive it.

(d) *Disposing of device.* Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator shall return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.

§ 812.119 Disqualification of a clinical investigator.

(a) If FDA has information indicating that an investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has repeatedly or deliberately submitted false information either to the sponsor of the investigation or in any required report, the Center for Devices and Radiological Health will furnish the investigator written notice of the matter under complaint and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the Center for Devices and Radiological Health, the disqualification process will be terminated. If an explanation is offered but not accepted by the Center for Devices and Radiological Health, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the question of whether the investigator is entitled to receive investigational devices.

(b) After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has deliberately or repeatedly submitted false information either to the sponsor of the investigation or in any required report, the Commissioner will notify the investigator, the sponsor of any investigation in which the investigator has been named as a participant, and the reviewing IRB that the investigator is not entitled to receive investigational devices. The notification will provide a statement of basis for such determination.

(c) Each investigational device exemption (IDE) and each cleared or approved application submitted under this part, subpart E of part 807 of this chapter, or part 814 of this chapter containing data reported by an investigator who has been determined to be ineligible to receive investigational devices will be examined to determine whether the investigator has submitted

unreliable data that are essential to the continuation of the investigation or essential to the approval or clearance of any marketing application.

(d) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, the Commissioner will notify the sponsor who shall have an opportunity for a regulatory hearing under part 16 of this chapter. If a danger to the public health exists, however, the Commissioner shall terminate the IDE immediately and notify the sponsor and the reviewing IRB of the determination. In such case, the sponsor shall have an opportunity for a regulatory hearing before FDA under part 16 of this chapter on the question of whether the IDE should be reinstated.

(e) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued clearance or approval of the marketing application for which the data were submitted cannot be justified, the Commissioner will proceed to withdraw approval or rescind clearance of the medical device in accordance with the applicable provisions of the act.

(f) An investigator who has been determined to be ineligible to receive investigational devices may be reinstated as eligible when the Commissioner determines that the investigator has presented adequate assurances that the investigator will employ investigational devices solely in compliance with the provisions of this part and of parts 50 and 56 of this chapter.

[62 FR 12096, Mar. 14, 1997]

EFFECTIVE DATE NOTE: At 62 FR 12096, Mar. 14, 1997, § 812.119 was added, effective May 13, 1997.

Subpart F [Reserved]**Subpart G—Records and Reports****§ 812.140 Records.**

(a) *Investigator records.* A participating investigator shall maintain the following accurate, complete, and current

records relating to the investigator's participation in an investigation:

(1) All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.

(2) Records of receipt, use or disposition of a device that relate to:

(i) The type and quantity of the device, the dates of its receipt, and the batch number or code mark.

(ii) The names of all persons who received, used, or disposed of each device.

(iii) Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.

(3) Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. Such records shall include:

(i) Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

(ii) All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.

(iii) A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.

(4) The protocol, with documents showing the dates of and reasons for each deviation from the protocol.

(5) Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

(b) *Sponsor records.* A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:

(1) All correspondence with another sponsor, a monitor, an investigator, an IRB, or FDA, including required reports.

(2) Records of shipment and disposition. Records of shipment shall include the name and address of the consignee, type and quantity of device, date of shipment, and batch number or code mark. Records of disposition shall describe the batch number or code marks of any devices returned to the sponsor, repaired, or disposed of in other ways by the investigator or another person, and the reasons for and method of disposal.

(3) Signed investigator agreements.

(4) For each investigation subject to § 812.2(b)(1) of a device other than a significant risk device, the records described in paragraph (b)(5) of this section and the following records, consolidated in one location and available for FDA inspection and copying:

(i) The name and intended use of the device and the objectives of the investigation;

(ii) A brief explanation of why the device is not a significant risk device;

(iii) The name and address of each investigator;

(iv) The name and address of each IRB that has reviewed the investigation;

(v) A statement of the extent to which the good manufacturing practice regulation in Part 820 will be followed in manufacturing the device; and

(vi) Any other information required by FDA.

(5) Records concerning adverse device effects (whether anticipated or unanticipated) and complaints and

(6) Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation.

(c) *IRB records.* An IRB shall maintain records in accordance with Part 56 of this chapter.

(d) *Retention period.* An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years

after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a pre-market approval application or a notice of completion of a product development protocol.

(e) *Records custody.* An investigator or sponsor may withdraw from the responsibility to maintain records for the period required in paragraph (d) of this section and transfer custody of the records to any other person who will accept responsibility for them under this part, including the requirements of § 812.145. Notice of a transfer shall be given to FDA not later than 10 working days after transfer occurs.

[45 FR 3751, Jan. 18, 1980, as amended at 45 FR 58843, Sept. 5, 1980; 46 FR 8957, Jan. 27, 1981; 61 FR 57280, Nov. 5, 1996]

§ 812.145 Inspections.

(a) *Entry and inspection.* A sponsor or an investigator who has authority to grant access shall permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).

(b) *Records inspection.* A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, shall permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.

(c) *Records identifying subjects.* An investigator shall permit authorized FDA employees to inspect and copy records that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.

§ 812.150 Reports.

(a) *Investigator reports.* An investigator shall prepare and submit the fol-

lowing complete, accurate, and timely reports:

(1) *Unanticipated adverse device effects.* An investigator shall submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.

(2) *Withdrawal of IRB approval.* An investigator shall report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.

(3) *Progress.* An investigator shall submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.

(4) *Deviations from the investigational plan.* An investigator shall notify the sponsor and the reviewing IRB (see § 56.108(a) (3) and (4)) of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such notice shall be given as soon as possible, but in no event later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB in accordance with § 812.35(a) also is required.

(5) *Informed consent.* If an investigator uses a device without obtaining informed consent, the investigator shall report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.

(6) *Final report.* An investigator shall, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.

(7) *Other.* An investigator shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

(b) *Sponsor reports.* A sponsor shall prepare and submit the following complete, accurate, and timely reports:

(1) *Unanticipated adverse device effects.* A sponsor who conducts an evaluation of an unanticipated adverse device effect under § 812.46(b) shall report the results of such evaluation to FDA and to all reviewing IRB's and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect as FDA requests.

(2) *Withdrawal of IRB approval.* A sponsor shall notify FDA and all reviewing IRB's and participating investigators of any withdrawal of approval of an investigation or a part of an investigation by a reviewing IRB within 5 working days after receipt of the withdrawal of approval.

(3) *Withdrawal of FDA approval.* A sponsor shall notify all reviewing IRB's and participating investigators of any withdrawal of FDA approval of the investigation, and shall do so within 5 working days after receipt of notice of the withdrawal of approval.

(4) *Current investigator list.* A sponsor shall submit to FDA, at 6-month intervals, a current list of the names and addresses of all investigators participating in the investigation. The sponsor shall submit the first such list 6 months after FDA approval.

(5) *Progress reports.* At regular intervals, and at least yearly, a sponsor shall submit progress reports to all reviewing IRB's. In the case of a significant risk device, the sponsor shall also submit progress reports to FDA.

(6) *Recall and device disposition.* A sponsor shall notify FDA and all reviewing IRB's of any request that an investigator return, repair, or otherwise dispose of any units of a device. Such notice shall occur within 30 working days after the request is made and shall state why the request was made.

(7) *Final report.* In the case of a significant risk device, the sponsor shall notify FDA within 30 working days of the completion or termination of the investigation and shall submit a final report to FDA and all reviewing the IRB's and participating investigators within 6 months after completion or termination. In the case of a device

that is not a significant risk device, the sponsor shall submit a final report to all reviewing IRB's within 6 months after termination or completion.

(8) *Informed consent.* A sponsor shall submit to FDA a copy of any report by an investigator under paragraph (a)(5) of this section of use of a device without obtaining informed consent, within 5 working days of receipt of notice of such use.

(9) *Significant risk device determinations.* If an IRB determines that a device is a significant risk device, and the sponsor had proposed that the IRB consider the device not to be a significant risk device, the sponsor shall submit to FDA a report of the IRB's determination within 5 working days after the sponsor first learns of the IRB's determination.

(10) *Other.* A sponsor shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

[45 FR 3751, Jan. 18, 1980, as amended at 45 FR 58843, Sept. 5, 1980; 48 FR 15622, Apr. 12, 1983]

PART 813 [RESERVED]

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

Subpart A—General

Sec.

814.1 Scope.

814.2 Purpose.

814.3 Definitions.

814.9 Confidentiality of data and information in a premarket approval application (PMA) file.

814.15 Research conducted outside the United States.

814.17 Service of orders.

814.19 Product development protocol (PDP).

Subpart B—Premarket Approval Application (PMA)

814.20 Application.

814.37 PMA amendments and resubmitted PMA's.

814.39 PMA supplements.

Subpart C—FDA Action on a PMA

814.40 Time frames for reviewing a PMA.

814.42 Filing a PMA.

814.44 Procedures for review of a PMA.

§ 814.1

- 814.45 Denial of approval of a PMA.
- 814.46 Withdrawal of approval of a PMA.
- 814.47 Temporary suspension of approval of a PMA.

Subpart D—Administrative Review [Reserved]

Subpart E—Postapproval Requirements

- 814.80 General.
- 814.82 Postapproval requirements.
- 814.84 Reports.

Subparts F–G [Reserved]

Subpart H—Humanitarian Use Devices

- 814.100 Purpose and scope.
- 814.102 Designation of HUD status.
- 814.104 Original applications.
- 814.106 HDE amendments and resubmitted HDE's.
- 814.108 Supplemental applications.
- 814.110 New indications for use.
- 814.112 Filing an HDE.
- 814.114 Timeframes for reviewing an HDE.
- 814.116 Procedures for review of an HDE.
- 814.118 Denial of approval or withdrawal of approval of an HDE.
- 814.120 Requests for extension.
- 814.122 Confidentiality of data and information.
- 814.124 Institutional Review Board requirements.
- 814.126 Postapproval requirements and reports.

AUTHORITY: Secs. 501, 502, 503, 510, 513–520, 701, 702, 703, 704, 705, 708, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381).

SOURCE: 51 FR 26364, July 22, 1986, unless otherwise noted.

Subpart A—General

§ 814.1 Scope.

(a) This part implements section 515 of the act by providing procedures for the premarket approval of medical devices intended for human use.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

(c) This part applies to any class III medical device, unless exempt under section 520(g) of the act, that:

(1) Was not on the market (introduced or delivered for introduction into commerce for commercial distribution) before May 28, 1976, and is not substan-

21 CFR Ch. I (4–1–97 Edition)

tially equivalent to a device on the market before May 28, 1976, or to a device first marketed on, or after that date, which has been classified into class I or class II; or

(2) Is required to have an approved premarket approval application (PMA) or a declared completed product development protocol under a regulation issued under section 515(b) of the act; or

(3) Was regulated by FDA as a new drug or antibiotic drug before May 28, 1976, and therefore is governed by section 520(1) of the act.

(d) This part amends the conditions to approval for any PMA approved before the effective date of this part. Any condition to approval for an approved PMA that is inconsistent with this part is revoked. Any condition to approval for an approved PMA that is consistent with this part remains in effect.

§ 814.2 Purpose.

The purpose of this part is to establish an efficient and thorough device review process—

(a) To facilitate the approval of PMA's for devices that have been shown to be safe and effective and that otherwise meet the statutory criteria for approval; and

(b) To ensure the disapproval of PMA's for devices that have not been shown to be safe and effective or that do not otherwise meet the statutory criteria for approval. This part shall be construed in light of these objectives.

§ 814.3 Definitions.

For the purposes of this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act (sections 201–902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321–392)).

(b) *FDA* means the Food and Drug Administration.

(c) *IDE* means an approved or considered approved investigational device exemption under section 520(g) of the act and Parts 812 and 813.

(d) *Master file* means a reference source that a person submits to FDA. A master file may contain detailed information on a specific manufacturing facility, process, methodology, or component used in the manufacture, processing, or packaging of a medical device.

(e) *PMA* means any premarket approval application for a class III medical device, including all information submitted with or incorporated by reference therein. "PMA" includes a new drug application for a device under section 520(1) of the act.

(f) *PMA amendment* means information an applicant submits to FDA to modify a pending PMA or a pending PMA supplement.

(g) *PMA supplement* means a supplemental application to an approved PMA for approval of a change or modification in a class III medical device, including all information submitted with or incorporated by reference therein.

(h) *Person* includes any individual, partnership, corporation, association, scientific or academic establishment, Government agency, or organizational unit thereof, or any other legal entity.

(i) *Statement of material fact* means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

(j) *30-day PMA supplement* means a supplemental application to an approved PMA in accordance with § 814.39(e).

(k) *Reasonable probability* means that it is more likely than not that an event will occur.

(l) *Serious, adverse health consequences* means any significant adverse experience, including those which may be either life-threatening or involve permanent or long term injuries, but excluding injuries that are nonlife-threatening and that are temporary and reasonably reversible.

(m) *HDE* means a premarket approval application submitted pursuant to this subpart seeking a humanitarian device exemption from the effectiveness requirements of sections 514 and 515 of the act as authorized by section 520(m)(2) of the act.

(n) *HUD (humanitarian use device)* means a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

[51 FR 26364, July 22, 1986, as amended at 61 FR 15190, Apr. 5, 1996; 61 FR 33244, June 26, 1996]

§ 814.9 Confidentiality of data and information in a premarket approval application (PMA) file.

(a) A "PMA file" includes all data and information submitted with or incorporated by reference in the PMA, any IDE incorporated into the PMA, any PMA supplement, any report under § 814.82, any master file, or any other related submission. Any record in the PMA file will be available for public disclosure in accordance with the provisions of this section and Part 20. The confidentiality of information in a color additive petition submitted as part of a PMA is governed by § 71.15.

(b) The existence of a PMA file may not be disclosed by FDA before an approval order is issued to the applicant unless it previously has been publicly disclosed or acknowledged.

(c) If the existence of a PMA file has not been publicly disclosed or acknowledged, data or information in the PMA file are not available for public disclosure.

(d)(1) If the existence of a PMA file has been publicly disclosed or acknowledged before an order approving, or an order denying approval of the PMA is issued, data or information contained in the file are not available for public disclosure before such order issues. FDA may, however, disclose a summary of portions of the safety and effectiveness data before an approval order or an order denying approval of the PMA issues if disclosure is relevant to public consideration of a specific pending issue.

(2) Notwithstanding paragraph (d)(1) of this section, FDA will make available to the public upon request the information in the IDE that was required to be filed in Docket Number 95S-0158 in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23,

Rockville, MD 20857, for investigations involving an exception from informed consent under § 50.24 of this chapter. Persons wishing to request this information shall submit a request under the Freedom of Information Act.

(e) Upon issuance of an order approving, or an order denying approval of any PMA, FDA will make available to the public the fact of the existence of the PMA and a detailed summary of information submitted to FDA respecting the safety and effectiveness of the device that is the subject of the PMA and that is the basis for the order.

(f) After FDA issues an order approving, or an order denying approval of any PMA, the following data and information in the PMA file are immediately available for public disclosure:

(1) All safety and effectiveness data and information previously disclosed to the public, as such disclosure is defined in § 20.81.

(2) Any protocol for a test or study unless the protocol is shown to constitute trade secret or confidential commercial or financial information under § 20.61.

(3) Any adverse reaction report, product experience report, consumer complaint, and other similar data and information, after deletion of:

(i) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61; and

(ii) Any personnel, medical, and similar information disclosure of which would constitute a clearly unwarranted invasion of personal privacy under § 20.63; provided, however, that except for the information that constitutes trade secret or confidential commercial or financial information under § 20.61, FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

(4) A list of components previously disclosed to the public, as such disclosure is defined in § 20.81.

(5) An assay method or other analytical method, unless it does not serve any regulatory purpose and is shown to fall within the exemption in § 20.61 for trade secret or confidential commercial or financial information.

(6) All correspondence and written summaries of oral discussions relating to the PMA file, in accordance with the provisions of §§ 20.103 and 20.104.

(g) All safety and effectiveness data and other information not previously disclosed to the public are available for public disclosure if any one of the following events occurs and the data and information do not constitute trade secret or confidential commercial or financial information under § 20.61:

(1) The PMA has been abandoned. FDA will consider a PMA abandoned if:

(i)(A) The applicant fails to respond to a request for additional information within 180 days after the date FDA issues the request or

(B) Other circumstances indicate that further work is not being undertaken with respect to it, and

(ii) The applicant fails to communicate with FDA within 7 days after the date on which FDA notifies the applicant that the PMA appears to have been abandoned.

(2) An order denying approval of the PMA has issued, and all legal appeals have been exhausted.

(3) An order withdrawing approval of the PMA has issued, and all legal appeals have been exhausted.

(4) The device has been reclassified.

(5) The device has been found to be substantially equivalent to a class I or class II device.

(6) The PMA is considered voluntarily withdrawn under § 814.44(g).

(h) The following data and information in a PMA file are not available for public disclosure unless they have been previously disclosed to the public, as such disclosure is defined in § 20.81, or they relate to a device for which a PMA has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which are not available for public disclosure under

this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

[51 FR 26364, July 22, 1986, as amended at 61 FR 51531, Oct. 2, 1996]

§814.15 Research conducted outside the United States.

(a) A study conducted outside the United States submitted in support of a PMA and conducted under an IDE shall comply with Part 812. A study conducted outside the United States submitted in support of a PMA and not conducted under an IDE shall comply with the provisions in paragraph (b) or (c) of this section, as applicable.

(b) *Research begun on or after effective date.* FDA will accept studies submitted in support of a PMA which have been conducted outside the United States and begun on or after November 19, 1986, if the data are valid and the investigator has conducted the studies in conformance with the "Declaration of Helsinki" or the laws and regulations of the country in which the research is conducted, whichever accords greater protection to the human subjects. If the standards of the country are used, the applicant shall state in detail any differences between those standards and the "Declaration of Helsinki" and explain why they offer greater protection to the human subjects.

(c) Research begun before effective date. FDA will accept studies submitted in support of a PMA which have been conducted outside the United States and begun before November 19, 1986, if FDA is satisfied that the data are scientifically valid and that the rights, safety, and welfare of human subjects have not been violated.

(d) *As sole basis for marketing approval.* A PMA based solely on foreign clinical data and otherwise meeting the criteria for approval under this part may be approved if:

(1) The foreign data are applicable to the U.S. population and U.S. medical practice;

(2) The studies have been performed by clinical investigators of recognized competence; and

(3) The data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such

an inspection to be necessary, FDA can validate the data through an on-site inspection or other appropriate means.

(e) *Consultation between FDA and applicants.* Applicants are encouraged to meet with FDA officials in a "presubmission" meeting when approval based solely on foreign data will be sought.

(Approved by the Office of Management and Budget under control number 0910-0231)

[51 FR 26364, July 22, 1986; 51 FR 40415, Nov. 7, 1986, as amended at 51 FR 43344, Dec. 2, 1986]

§814.17 Service of orders.

Orders issued under this part will be served in person by a designated officer or employee of FDA on, or by registered mail to, the applicant or the designated agent at the applicant's or designated agent's last known address in FDA's records.

§814.19 Product development protocol (PDP).

A class III device for which a product development protocol has been declared completed by FDA under this chapter will be considered to have an approved PMA.

Subpart B—Premarket Approval Application (PMA)

§814.20 Application.

(a) The applicant or an authorized representative shall sign the PMA. If the applicant does not reside or have a place of business within the United States, the PMA shall be countersigned by an authorized representative residing or maintaining a place of business in the United States and shall identify the representative's name and address.

(b) Unless the applicant justifies an omission in accordance with paragraph (d) of this section, a PMA shall include:

(1) The name and address of the applicant.

(2) A table of contents that specifies the volume and page number for each item referred to in the table. A PMA shall include separate sections on non-clinical laboratory studies and on clinical investigations involving human subjects. A PMA shall be submitted in six copies each bound in one or more

numbered volumes of reasonable size. The applicant shall include information that it believes to be trade secret or confidential commercial or financial information in all copies of the PMA and identify in at least one copy the information that it believes to be trade secret or confidential commercial or financial information.

(3) A summary in sufficient detail that the reader may gain a general understanding of the data and information in the application. The summary shall contain the following information:

(i) *Indications for use.* A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

(ii) *Device description.* An explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device. A brief description of the manufacturing process should be included if it will significantly enhance the reader's understanding of the device. The generic name of the device as well as any proprietary name or trade name should be included.

(iii) *Alternative practices and procedures.* A description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.

(iv) *Marketing history.* A brief description of the foreign and U.S. marketing history, if any, of the device, including a list of all countries in which the device has been marketed and a list of all countries in which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device. The description shall include the history of the marketing of the device by the applicant and, if known, the history of the marketing of the device by any other person.

(v) *Summary of studies.* An abstract of any information or report described in the PMA under paragraph (b)(8)(ii) of this section and a summary of the results of technical data submitted under paragraph (b)(6) of this section. Such

summary shall include a description of the objective of the study, a description of the experimental design of the study, a brief description of how the data were collected and analyzed, and a brief description of the results, whether positive, negative, or inconclusive. This section shall include the following:

(A) A summary of the nonclinical laboratory studies submitted in the application;

(B) A summary of the clinical investigations involving human subjects submitted in the application including a discussion of subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, results of statistical analyses of the clinical investigations, contraindications and precautions for use of the device, and other information from the clinical investigations as appropriate (any investigation conducted under an IDE shall be identified as such).

(vi) *Conclusions drawn from the studies.* A discussion demonstrating that the data and information in the application constitute valid scientific evidence within the meaning of § 860.7 and provide reasonable assurance that the device is safe and effective for its intended use. A concluding discussion shall present benefit and risk considerations related to the device including a discussion of any adverse effects of the device on health and any proposed additional studies or surveillance the applicant intends to conduct following approval of the PMA.

(4) A complete description of:

(i) The device, including pictorial representations;

(ii) Each of the functional components or ingredients of the device if the device consists of more than one physical component or ingredient;

(iii) The properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition;

(iv) The principles of operation of the device; and

(v) The methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device.

(5) Reference to any performance standard under section 514 of the act or the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b et seq.) in effect or proposed at the time of the submission and to any voluntary standard that is relevant to any aspect of the safety or effectiveness of the device and that is known to or that should reasonably be known to the applicant. The applicant shall—

(i) Provide adequate information to demonstrate how the device meets, or justify any deviation from, any performance standard established under section 514 of the act or under the Radiation Control for Health and Safety Act, and

(ii) Explain any deviation from a voluntary standard.

(6) The following technical sections which shall contain data and information in sufficient detail to permit FDA to determine whether to approve or deny approval of the application:

(i) A section containing results of the nonclinical laboratory studies with the device including microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests as appropriate. Information on nonclinical laboratory studies shall include a statement that each such study was conducted in compliance with Part 58, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(ii) A section containing results of the clinical investigations involving human subjects with the device including clinical protocols, number of investigators and subjects per investigator, subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints,

device failures and replacements, tabulations of data from all individual subject report forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation, results of statistical analyses of the clinical investigations, device failures and replacements, contraindications and precautions for use of the device, and any other appropriate information from the clinical investigations. Any investigation conducted under an IDE shall be identified as such. Information on clinical investigations involving human subjects shall include the following:

(A) A statement with respect to each study that it either was conducted in compliance with the institutional review board regulations in Part 56, or was not subject to the regulations under § 56.104 or § 56.105, and that it was conducted in compliance with the informed consent regulations in Part 50; or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(B) A statement that each study was conducted in compliance with Part 812 or Part 813 concerning sponsors of clinical investigations and clinical investigators, or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(7) For a PMA supported solely by data from one investigation, a justification showing that data and other information from a single investigator are sufficient to demonstrate the safety and effectiveness of the device and to ensure reproducibility of test results.

(8)(i) A bibliography of all published reports not submitted under paragraph (b)(6) of this section, whether adverse or supportive, known to or that should reasonably be known to the applicant and that concern the safety or effectiveness of the device.

(ii) An identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any source, foreign or domestic,

including information derived from investigations other than those proposed in the application and from commercial marketing experience.

(iii) Copies of such published reports or unpublished information in the possession of or reasonably obtainable by the applicant if an FDA advisory committee or FDA requests.

(9) One or more samples of the device and its components, if requested by FDA. If it is impractical to submit a requested sample of the device, the applicant shall name the location at which FDA may examine and test one or more devices.

(10) Copies of all proposed labeling for the device. Such labeling may include, e.g., instructions for installation and any information, literature, or advertising that constitutes labeling under section 201(m) of the act.

(11) An environmental assessment under § 25.22(a)(18) prepared in the applicable format in § 25.31, unless the action qualifies for exclusion under § 25.24(e) (4) or (5). If the applicant believes that the action qualifies for exclusion, the PMA shall under § 25.23(c) provide information that establishes to FDA's satisfaction that the action requested is included within the excluded category and meets the criteria for the applicable exclusion.

(12) Such other information as FDA may request. If necessary, FDA will obtain the concurrence of the appropriate FDA advisory committee before requesting additional information.

(c) Pertinent information in FDA files specifically referred to by an applicant may be incorporated into a PMA by reference. Information in a master file or other information submitted to FDA by a person other than the applicant will not be considered part of a PMA unless such reference is authorized in writing by the person who submitted the information or the master file. If a master file is not referenced within 5 years after the date that it is submitted to FDA, FDA will return the master file to the person who submitted it.

(d) If the applicant believes that certain information required under paragraph (b) of this section to be in a PMA is not applicable to the device that is the subject of the PMA, and omits any

such information from its PMA, the applicant shall submit a statement that identifies the omitted information and justifies the omission. The statement shall be submitted as a separate section in the PMA and identified in the table of contents. If the justification for the omission is not accepted by the agency, FDA will so notify the applicant.

(e) The applicant shall periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies that may reasonably affect an evaluation of the safety or effectiveness of the device or that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling. The update report shall be consistent with the data reporting provisions of the protocol. The applicant shall submit three copies of any update report and shall include in the report the number assigned by FDA to the PMA. These updates are considered to be amendments to the PMA. The time frame for review of a PMA will not be extended due to the submission of an update report unless the update is a major amendment under § 814.37(c)(1). The applicant shall submit these reports—

(1) 3 months after the filing date,

(2) Following receipt of an approvable letter, and

(3) At any other time as requested by FDA.

(f) If a color additive subject to section 706 of the act is used in or on the device and has not previously been listed for such use, then, in lieu of submitting a color additive petition under Part 71, at the option of the applicant, the information required to be submitted under Part 71 may be submitted as part of the PMA. When submitted as part of the PMA, the information shall be submitted in three copies each bound in one or more numbered volumes of reasonable size. A PMA for a device that contains a color additive that is subject to section 706 of the act will not be approved until the color additive is listed for use in or on the device.

(g) FDA has issued a PMA guideline to assist the applicant in the arrangement and content of a PMA. This guideline is available from the Center for Devices and Radiological Health, Office of Standards and Regulations (HFZ-80), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(h) A PMA, PMA amendment, PMA supplement, or correspondence with respect to a PMA shall be sent to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850.

(Approved by the Office of Management and Budget under control number 0910-0231)

[51 FR 26364, July 22, 1986; 51 FR 40415, Nov. 7, 1986, as amended at 51 FR 43344, Dec. 2, 1986; 55 FR 11169, Mar. 27, 1990]

§ 814.37 PMA amendments and resubmitted PMA's.

(a) An applicant may amend a pending PMA or PMA supplement to revise existing information or provide additional information.

(b) FDA may request the applicant to amend a PMA or PMA supplement with any information regarding the device that is necessary for FDA or the appropriate advisory committee to complete the review of the PMA or PMA supplement.

(c) A PMA amendment submitted to FDA shall include the PMA or PMA supplement number assigned to the original submission and, if submitted on the applicant's own initiative, the reason for submitting the amendment. FDA may extend the time required for its review of the PMA, or PMA supplement, as follows:

(1) If the applicant on its own initiative or at FDA's request submits a major PMA amendment (e.g., an amendment that contains significant new data from a previously unreported study, significant updated data from a previously reported study, detailed new analyses of previously submitted data, or significant required information previously omitted), the review period may be extended up to 180 days.

(2) If an applicant declines to submit a major amendment requested by FDA, the review period may be extended for

the number of days that elapse between the date of such request and the date that FDA receives the written response declining to submit the requested amendment.

(d) An applicant may on its own initiative withdraw a PMA or PMA supplement. If FDA requests an applicant to submit a PMA amendment and a written response to FDA's request is not received within 180 days of the date of the request, FDA will consider the pending PMA or PMA supplement to be withdrawn voluntarily by the applicant.

(e) An applicant may resubmit a PMA or PMA supplement after withdrawing it or after it is considered withdrawn under paragraph (d) of this section, or after FDA has refused to accept it for filing, or has denied approval of the PMA or PMA supplement. A resubmitted PMA or PMA supplement shall comply with the requirements of § 814.20 or § 814.39, respectively, and shall include the PMA number assigned to the original submission and the applicant's reasons for resubmission of the PMA or PMA supplement.

§ 814.39 PMA supplements.

(a) After FDA approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA, unless the change is of a type for which FDA, under paragraph (e) of this section, has advised that an alternate submission is permitted. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include but are not limited to the following types of changes if they affect the safety or effectiveness of the device:

(1) New indications for use of the device.

(2) Labeling changes.

(3) The use of a different facility or establishment to manufacture, process, or package the device.

(4) Changes in manufacturing facilities, methods, or quality control procedures.

(5) Changes in sterilization procedures.

(6) Changes in packaging.

(7) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.

(8) Extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that has not been approved by FDA. If the protocol has been approved, the change shall be reported to FDA under paragraph (b) of this section.

(b) An applicant may make a change in a device after FDA's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device's safety or effectiveness and the change is reported to FDA in postapproval periodic reports required as a condition to approval of the device, e.g., an editorial change in labeling which does not affect the safety or effectiveness of the device.

(c) All procedures and actions that apply to an application under §814.20 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change. A summary under §814.20(b)(3) is required for only a supplement submitted for new indications for use of the device, significant changes in the performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device, or when otherwise required by FDA. The applicant shall submit three copies of a PMA supplement and shall include information relevant to the proposed changes in the device. A PMA supplement shall include a separate section that identifies each change for which approval is being requested and explains the reason for each such change. The applicant shall submit additional copies and additional information if requested by FDA. The time frames for review of, and FDA action on, a PMA supplement are the same as those provided in §814.40 for a PMA.

(d)(1) After FDA approves a PMA, any change described in paragraph (d)(2) of this section that enhances the safety of the device or the safety in the use of the device may be placed into ef-

fect by the applicant prior to the receipt under §814.17 of a written FDA order approving the PMA supplement provided that:

(i) The PMA supplement and its mailing cover are plainly marked "Special PMA Supplement—Changes Being Effected";

(ii) The PMA supplement provides a full explanation of the basis for the changes;

(iii) The applicant has received acknowledgement from FDA of receipt of the supplement; and

(iv) The PMA supplement specifically identifies the date that such changes are being effected.

(2) The following changes are permitted by paragraph (d)(1) of this section:

(i) Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction.

(ii) Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device.

(iii) Labeling changes that delete misleading, false, or unsupported indications.

(iv) Changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

(e) FDA will identify a change to a device for which an applicant has an approved PMA and for which a PMA supplement under paragraph (a) is not required. FDA will identify such a change in an advisory opinion under §10.85, if the change applies to a generic type of device, or in correspondence to the applicant, if the change applies only to the applicant's device. FDA will require that a change for which a PMA supplement under paragraph (a) is not required be reported to FDA in—

(1) A periodic report under §814.84 or

(2) A 30-day PMA supplement under this paragraph.

FDA will identify, in the advisory opinion or correspondence, the type of information that is to be included in the report or 30-day PMA supplement. If the change is required to be reported to

FDA in a periodic report, the change may be made before it is reported to FDA. If the change is required to be reported in a 30-day PMA supplement, the change may be made 30 days after FDA files the 30-day PMA supplement unless FDA requires the PMA holder to provide additional information, informs the PMA holder that the supplement is not approvable, or disapproves the supplement. The 30-day PMA supplement shall follow the instructions in the correspondence or advisory opinion. Any 30-day PMA supplement that does not meet the requirements of the correspondence or advisory opinion will not be filed and, therefore, will not be deemed approved 30 days after receipt.

(Approved by the Office of Management and Budget under control number 0910-0231)

[51 FR 26364, July 22, 1986, as amended at 51 FR 43344, Dec. 2, 1986]

Subpart C—FDA Action on a PMA

§ 814.40 Time frames for reviewing a PMA.

Within 180 days after receipt of an application that is accepted for filing and to which the applicant does not submit a major amendment, FDA will review the PMA and, after receiving the report and recommendation of the appropriate FDA advisory committee, send the applicant an approval order under § 814.44(d), an approvable letter under § 814.44(e), a not approvable letter under § 814.44(f), or an order denying approval under § 814.45. The approvable letter and the not approvable letter will provide an opportunity for the applicant to amend or withdraw the application, or to consider the letter to be a denial of approval of the PMA under § 814.45 and to request administrative review under section 515 (d)(3) and (g) of the act.

§ 814.42 Filing a PMA.

(a) The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review. Within 45 days after a PMA is received by FDA, the agency will notify the applicant whether the application has been filed.

(b) If FDA does not find that any of the reasons in paragraph (e) of this section for refusing to file the PMA applies, the agency will file the PMA and will notify the applicant in writing of the filing. The notice will include the PMA reference number and the date FDA filed the PMA. The date of filing is the date that a PMA accepted for filing was received by the agency. The 180-day period for review of a PMA starts on the date of filing.

(c) If FDA refuses to file a PMA, the agency will notify the applicant of the reasons for the refusal. This notice will identify the deficiencies in the application that prevent filing and will include the PMA reference number.

(d) If FDA refuses to file the PMA, the applicant may:

(1) Resubmit the PMA with additional information necessary to comply with the requirements of section 515(c)(1) (A)–(G) of the act and § 814.20. A resubmitted PMA shall include the PMA reference number of the original submission. If the resubmitted PMA is accepted for filing, the date of filing is the date FDA receives the resubmission;

(2) Request in writing within 10 working days of the date of receipt of the notice refusing to file the PMA, an informal conference with the Director of the Office of Device Evaluation to review FDA's decision not to file the PMA. FDA will hold the informal conference within 10 working days of its receipt of the request and will render its decision on filing within 5 working days after the informal conference. If, after the informal conference, FDA accepts the PMA for filing, the date of filing will be the date of the decision to accept the PMA for filing. If FDA does not reverse its decision not to file the PMA, the applicant may request reconsideration of the decision from the Director of the Center for Devices and Radiological Health. The Director's decision will constitute final administrative action for the purpose of judicial review.

(e) FDA may refuse to file a PMA if any of the following applies:

(1) The application is incomplete because it does not on its face contain all the information required under section 515(c)(1) (A)–(G) of the act;

(2) The PMA does not contain each of the items required under § 814.20 and justification for omission of any item is inadequate;

(3) The applicant has a pending pre-market notification under section 510(k) of the act with respect to the same device, and FDA has not determined whether the device falls within the scope of § 814.1(c).

(4) The PMA contains a false statement of material fact.

§ 814.44 Procedures for review of a PMA.

(a) FDA will begin substantive review of a PMA after the PMA is accepted for filing under § 814.42. FDA may refer the PMA to a panel on its own initiative, and will do so upon request of an applicant, unless FDA determines that the application substantially duplicates information previously reviewed by a panel. If FDA refers an application to a panel, FDA will forward the PMA, or relevant portions thereof, to each member of the appropriate FDA panel for review. During the review process, FDA may communicate with the applicant as set forth under § 814.37(b), or with a panel to respond to questions that may be posed by panel members or to provide additional information to the panel. FDA will maintain a record of all communications with the applicant and with the panel.

(b) The advisory committee shall submit a report to FDA which includes the committee's recommendation and the basis for such recommendation on the PMA. Before submission of this report, the committee shall hold a public meeting to review the PMA in accordance with Part 14. This meeting may be held by a telephone conference under § 14.22(g). The advisory committee report and recommendation may be in the form of a meeting transcript signed by the chairperson of the committee.

(c) FDA will complete its review of the PMA and the advisory committee report and recommendation and, within the later of 180 days from the date of filing of the PMA under § 814.42 or the number of days after the date of filing as determined under § 814.37(c), issue an approval order under paragraph (d) of this section, an approvable letter under paragraph (e) of this section, a not ap-

provable letter under paragraph (f) of this section, or an order denying approval of the application under § 814.45(a).

(d) FDA will issue to the applicant an order approving a PMA if none of the reasons in § 814.45 for denying approval of the application applies. FDA will approve an application on the basis of draft final labeling if the only deficiencies in the application concern editorial or similar minor deficiencies in the draft final labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed and upon the applicant submitting to FDA a copy of the final printed labeling before marketing. FDA also will give the public notice of the order, including notice of an opportunity for any interested person to request review under section 515(d)(3) of the act. The notice of approval will be published in the FEDERAL REGISTER and will state that a detailed summary of information respecting the safety and effectiveness of the device which was the basis for the order approving the PMA, including information about any adverse effects of the device on health, has been placed on public display and that copies are available upon request. When a notice of approval is published, data and information in the PMA file will be available for public disclosure in accordance with § 814.9.

(e) FDA will send the applicant an approvable letter if the application substantially meets the requirements of this part and the agency believes it can approve the application if specific additional information is submitted or specific conditions are agreed to by the applicant.

(1) The approvable letter will describe the information FDA requires to be provided by the applicant or the conditions the applicant is required to meet to obtain approval. For example, FDA may require, as a condition to approval:

(i) The submission of certain information identified in the approvable letter, e.g., final labeling;

(ii) An FDA inspection that finds the manufacturing facilities, methods, and controls in compliance with Part 820

and, if applicable, that verifies records pertinent to the PMA;

(iii) Restrictions imposed on the device under section 515(d)(1)(B)(ii) or 520(e) of the act;

(iv) Postapproval requirements as described in Subpart E of this part.

(2) In response to an approvable letter the applicant may:

(i) Amend the PMA as requested in the approvable letter; or

(ii) Consider the approvable letter to be a denial of approval of the PMA under § 814.45 and request administrative review under section 515(d)(3) of the act by filing a petition in the form of a petition for reconsideration under § 10.33; or

(iii) Withdraw the PMA.

(f) FDA will send the applicant a not approvable letter if the agency believes that the application may not be approved for one or more of the reasons given in § 814.45(a). The not approvable letter will describe the deficiencies in the application, including each applicable ground for denial under section 515(d)(2) (A)–(E) of the act, and, where practical, will identify measures required to place the PMA in approvable form. In response to a not approvable letter, the applicant may:

(1) Amend the PMA as requested in the not approvable letter (such an amendment will be considered a major amendment under § 814.37(c)(1)); or

(2) Consider the not approvable letter to be a denial of approval of the PMA under § 814.45 and request administrative review under section 515(d)(3) of the act by filing a petition in the form of a petition for reconsideration under § 10.33; or

(3) Withdraw the PMA.

(g) FDA will consider a PMA to have been withdrawn voluntarily if:

(1) The applicant fails to respond in writing to a written request for an amendment within 180 days after the date FDA issues such request;

(2) The applicant fails to respond in writing to an approvable or not approvable letter within 180 days after the date FDA issues such letter; or

(3) The applicant submits a written notice to FDA that the PMA has been withdrawn.

[51 FR 26364, July 22, 1986, as amended at 57 FR 58403, Dec. 10, 1992]

§ 814.45 Denial of approval of a PMA.

(a) FDA may issue an order denying approval of a PMA if the applicant fails to follow the requirements of this part or if, upon the basis of the information submitted in the PMA or any other information before the agency, FDA determines that any of the grounds for denying approval of a PMA specified in section 515(d)(2) (A)–(E) of the act applies. In addition, FDA may deny approval of a PMA for any of the following reasons:

(1) The PMA contains a false statement of material fact;

(2) The device's proposed labeling does not comply with the requirements in Part 801 or Part 809;

(3) The applicant does not permit an authorized FDA employee an opportunity to inspect at a reasonable time and in a reasonable manner the facilities, controls, and to have access to and to copy and verify all records pertinent to the application;

(4) A nonclinical laboratory study that is described in the PMA and that is essential to show that the device is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations in Part 58 and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study; or

(5) Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations in Part 56 or informed consent regulations in Part 50, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(b) FDA will issue any order denying approval of the PMA in accordance with § 814.17. The order will inform the applicant of the deficiencies in the PMA, including each applicable ground for denial under section 515(d)(2) of the act and the regulations under this part, and, where practical, will identify measures required to place the PMA in approvable form. The order will include a notice of an opportunity to request

review under section 515(d)(3) of the act.

(c) FDA will use the criteria specified in §860.7 to determine the safety and effectiveness of a device in deciding whether to approve or deny approval of a PMA. FDA may use information other than that submitted by the applicant in making such determination.

(d) FDA will give the public notice of an order denying approval of the PMA. The notice will be published in the FEDERAL REGISTER and will state that a detailed summary of information respecting the safety and effectiveness of the device, including information about any adverse effects of the device on health, has been placed on public display and that copies are available upon request. When a notice of denial of approval is made publicly available, data and information in the PMA file will be available for public disclosure in accordance with §814.9.

(e) FDA will issue an order denying approval of a PMA after an approvable or not approvable letter has been sent and the applicant:

(1) Submits a requested amendment but any ground for denying approval of the application under section 515(d)(2) of the act still applies; or

(2) Notifies FDA in writing that the requested amendment will not be submitted; or

(3) Petitions for review under section 515(d)(3) of the act by filing a petition in the form of a petition for reconsideration under §10.33.

§814.46 Withdrawal of approval of a PMA.

(a) FDA may issue an order withdrawing approval of a PMA if, from any information available to the agency, FDA determines that:

(1) Any of the grounds under section 515(e)(1) (A)–(G) of the act applies.

(2) Any postapproval requirement imposed by the PMA approval order or by regulation has not been met.

(3) A nonclinical laboratory study that is described in the PMA and that is essential to show that the device is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations in Part

58 and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(4) Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations in Part 56 or informed consent regulations in Part 50, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(b)(1) FDA may seek advice on scientific matters from any appropriate FDA advisory committee in deciding whether to withdraw approval of a PMA.

(2) FDA may use information other than that submitted by the applicant in deciding whether to withdraw approval of a PMA.

(c) Before issuing an order withdrawing approval of a PMA, FDA will issue the holder of the approved application a notice of opportunity for an informal hearing under Part 16.

(d) If the applicant does not request a hearing or if after the Part 16 hearing is held the agency decides to proceed with the withdrawal, FDA will issue to the holder of the approved application an order withdrawing approval of the application. The order will be issued under §814.17, will state each ground for withdrawing approval, and will include a notice of an opportunity for administrative review under section 515(e)(2) of the act.

(e) FDA will give the public notice of an order withdrawing approval of a PMA. The notice will be published in the FEDERAL REGISTER and will state that a detailed summary of information respecting the safety and effectiveness of the device, including information about any adverse effects of the device on health, has been placed on public display and that copies are available upon request. When a notice of withdrawal of approval is published, data and information in the PMA file will be available for public disclosure in accordance with §814.9.

§ 814.47 Temporary suspension of approval of a PMA.

(a) *Scope.* (1) This section describes the procedures that FDA will follow in exercising its authority under section 515(e)(3) of the act (21 U.S.C. 360e(e)(3)). This authority applies to the original PMA, as well as any PMA supplement(s), for a medical device.

(2) FDA will issue an order temporarily suspending approval of a PMA if FDA determines that there is a reasonable probability that continued distribution of the device would cause serious, adverse health consequences or death.

(b) *Regulatory hearing.* (1) If FDA believes that there is a reasonable probability that the continued distribution of a device subject to an approved PMA would cause serious, adverse health consequences or death, FDA may initiate and conduct a regulatory hearing to determine whether to issue an order temporarily suspending approval of the PMA.

(2) Any regulatory hearing to determine whether to issue an order temporarily suspending approval of a PMA shall be initiated and conducted by FDA pursuant to part 16 of this chapter. If FDA believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, the agency may, in accordance with § 16.60(h) of this chapter, waive, suspend, or modify any part 16 procedure pursuant to § 10.19 of this chapter.

(3) FDA shall deem the PMA holder's failure to request a hearing within the timeframe specified by FDA in the notice of opportunity for hearing to be a waiver.

(c) *Temporary suspension order.* If the PMA holder does not request a regulatory hearing or if, after the hearing, and after consideration of the administrative record of the hearing, FDA determines that there is a reasonable probability that the continued distribution of a device under an approved PMA would cause serious, adverse health consequences or death, the agency shall, under the authority of section 515(e)(3) of the act, issue an order to the PMA holder temporarily suspending approval of the PMA.

(d) *Permanent withdrawal of approval of the PMA.* If FDA issues an order temporarily suspending approval of a PMA, the agency shall proceed expeditiously, but within 60 days, to hold a hearing on whether to permanently withdraw approval of the PMA in accordance with section 515(e)(1) of the act and the procedures set out in § 814.46.

[61 FR 15190, Apr. 5, 1996]

**Subpart D—Administrative Review
[Reserved]****Subpart E—Postapproval
Requirements****§ 814.80 General.**

A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.

§ 814.82 Postapproval requirements.

(a) FDA may impose postapproval requirements in a PMA approval order or by regulation at the time of approval of the PMA or by regulation subsequent to approval. Postapproval requirements may include as a condition to approval of the device:

(1) Restriction of the sale, distribution, or use of the device as provided by section 515(d)(1)(B)(ii) or 520(e) of the act.

(2) Continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. FDA will state in the PMA approval order the reason or purpose for such requirement and the number of patients to be evaluated and the reports required to be submitted.

(3) Prominent display in the labeling of a device and in the advertising of any restricted device of warnings, hazards, or precautions important for the device's safe and effective use, including patient information, e.g., information provided to the patient on alternative modes of therapy and on risks and benefits associated with the use of the device.

(4) Inclusion of identification codes on the device or its labeling, or in the case of an implant, on cards given to

patients if necessary to protect the public health.

(5) Maintenance of records that will enable the applicant to submit to FDA information needed to trace patients if such information is necessary to protect the public health. Under section 519(a)(4) of the act, FDA will require that the identity of any patient be disclosed in records maintained under this paragraph only to the extent required for the medical welfare of the individual, to determine the safety or effectiveness of the device, or to verify a record, report, or information submitted to the agency.

(6) Maintenance of records for specified periods of time and organization and indexing of records into identifiable files to enable FDA to determine whether there is reasonable assurance of the continued safety and effectiveness of the device.

(7) Submission to FDA at intervals specified in the approval order of periodic reports containing the information required by § 814.84(b).

(8) Batch testing of the device.

(9) Such other requirements as FDA determines are necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device.

(b) An applicant shall grant to FDA access to any records and reports required under the provisions of this part, and shall permit authorized FDA employees to copy and verify such records and reports and to inspect at a reasonable time and in a reasonable manner all manufacturing facilities to verify that the device is being manufactured, stored, labeled, and shipped under approved conditions.

(c) Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA.

(Approved by the Office of Management and Budget under control number 0910–0231)

[51 FR 26364, July 22, 1986, as amended at 51 FR 43344, Dec. 2, 1986]

§ 814.84 Reports.

(a) The holder of an approved PMA shall comply with the requirements of Part 803 and with any other requirements applicable to the device by other

regulations in this subchapter or by order approving the device.

(b) Unless FDA specifies otherwise, any periodic report shall:

(1) Identify changes described in § 814.39(a) and changes required to be reported to FDA under § 814.39(b).

(2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA:

(i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.

(ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted.

(Approved by the Office of Management and Budget under control number 0910–0231)

[51 FR 26364, July 22, 1986, as amended at 51 FR 43344, Dec. 2, 1986]

Subparts F–G [Reserved]

Subpart H—Humanitarian Use Devices

SOURCE: 61 FR 33244, June 26, 1996, unless otherwise noted.

§ 814.100 Purpose and scope.

(a) This subpart H implements section 520(m) of the act. The purpose of section 520(m) is, to the extent consistent with the protection of the public health and safety and with ethical standards, to encourage the discovery and use of devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in fewer than 4,000 individuals in the United States per year. This subpart provides procedures for obtaining:

(1) HUD designation of a medical device; and

(2) Temporary marketing approval for the HUD notwithstanding the absence of reasonable assurance of effectiveness that would otherwise be required under sections 514 and 515 of the act.

(b) Although a HUD may also have uses that differ from the humanitarian use, applicants seeking approval of any non-HUD use shall submit a PMA as required under § 814.20, or a premarket notification as required under part 807 of this chapter.

(c) Obtaining marketing approval for a HUD involves two steps:

(1) Obtaining designation of the device as a HUD from FDA's Office of Orphan Products Development, and

(2) Submitting an HDE to the Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH).

(d) The approval by ODE of an HDE under this subpart H shall be effective for a period of 18 months from the date of the approval letter, and shall permit the applicant to market the HUD in the United States in accordance with the restrictions described in this subpart H. Extensions of the approval may be granted in accordance with this subpart H.

§ 814.102 Designation of HUD status.

(a) *Request for designation.* Prior to submitting an HDE application, the applicant shall submit a request for HUD designation to FDA's Office of Orphan Products Development. The request shall contain the following:

(1) A statement that the applicant requests HUD designation for a rare disease or condition or a valid subset of a disease or condition which shall be identified with specificity;

(2) The name and address of the applicant, the name of the applicant's primary contact person and/or resident agent, including title, address, and telephone number;

(3) A description of the rare disease or condition for which the device is to be used, the proposed indication or indications for use of the device, and the reasons why such therapy is needed. If the device is proposed for an indication that represents a subset of a common disease or condition, a demonstration

that the subset is medically plausible should be included;

(4) A description of the device and a discussion of the scientific rationale for the use of the device for the rare disease or condition; and

(5) Documentation, with appended authoritative references, to demonstrate that the device is designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 people in the United States per year. If the device is for diagnostic purposes, the documentation must demonstrate that fewer than 4,000 patients per year would be subjected to diagnosis by the device in the United States. Authoritative references include literature citations in specialized medical journals, textbooks, specialized medical society proceedings, or governmental statistics publications. When no such studies or literature citations exist, the applicant may be able to demonstrate the prevalence of the disease or condition in the United States by providing credible conclusions from appropriate research or surveys.

(b) *FDA action.* Within 45 days of receipt of a request for HUD designation, FDA will take one of the following actions:

(1) Approve the request and notify the applicant that the device has been designated as a HUD based on the information submitted;

(2) Return the request to the applicant pending further review upon submission of additional information. This action will ensue if the request is incomplete because it does not on its face contain all of the information required under § 814.102(a). Upon receipt of this additional information, the review period may be extended up to 45 days; or

(3) Disapprove the request for HUD designation based on a substantive review of the information submitted. FDA may disapprove a request for HUD designation if:

(i) There is insufficient evidence to support the estimate that the disease or condition for which the device is designed to treat or diagnose affects or is manifested in fewer than 4,000 people in the United States per year;

(ii) FDA determines that, for a diagnostic device, 4,000 or more patients in

the United States would be subjected to diagnosis using the device per year; or

(iii) FDA determines that the patient population defined in the request is not a medically plausible subset of a larger population.

(c) *Revocation of designation.* FDA may revoke a HUD designation if the agency finds that:

(1) The request for designation contained an untrue statement of material fact or omitted material information; or

(2) Based on the evidence available, the device is not eligible for HUD designation.

(d) *Submission.* The applicant shall submit two copies of a completed, dated, and signed request for HUD designation to: Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, § 814.102 was stayed. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 814.104 Original applications.

(a) *United States applicant or representative.* The applicant or an authorized representative shall sign the HDE. If the applicant does not reside or have a place of business within the United States, the HDE shall be countersigned by an authorized representative residing or maintaining a place of business in the United States and shall identify the representative's name and address.

(b) *Time for submission.* An original HDE may only be submitted to the agency between October 24, 1996, and April 27, 2001, unless otherwise permitted by statute.

(c) *Contents.* Unless the applicant justifies an omission in accordance with paragraph (d) of this section, an HDE shall include:

(1) A copy of or reference to the determination made by FDA's Office of Orphan Products Development (in accordance with § 814.102) that the device qualifies as a HUD;

(2) An explanation of why the device would not be available unless an HDE were granted and a statement that no

comparable device (other than another HUD approved under this subpart or a device under an approved IDE) is available to treat or diagnose the disease or condition. The application also shall contain a discussion of the risks and benefits of currently available devices or alternative forms of treatment in the United States;

(3) An explanation of why the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Such explanation shall include a description, explanation, or theory of the underlying disease process or condition, and known or postulated mechanism(s) of action of the device in relation to the disease process or condition;

(4) All of the information required to be submitted under § 814.20(b), except that:

(i) In lieu of the summaries, conclusions, and results from clinical investigations required under §§ 814.20(b)(3)(v)(B), (b)(3)(vi), and (b)(6)(ii), the applicant shall include the summaries, conclusions, and results of all clinical experience or investigations (whether adverse or supportive) reasonably obtainable by the applicant that are relevant to an assessment of the risks and probable benefits of the device; and

(ii) In addition to the proposed labeling requirement set forth in § 814.20(b)(10), the labeling shall bear the following statement: Humanitarian Device. Authorized by Federal law for use in the [treatment or diagnosis] of [specify disease or condition]. The effectiveness of this device for this use has not been demonstrated; and

(5) The amount to be charged for the device and a report by an independent certified public accountant, made in accordance with the Statement on Standards for Attestation established by the American Institute of Certified Public Accountants, verifying that the amount charged does not exceed the costs of the device's research, development, fabrication, and distribution.

(d) *Omission of information.* If the applicant believes that certain information required under paragraph (c) of

this section is not applicable to the device that is the subject of the HDE, and omits any such information from its HDE, the applicant shall submit a statement that identifies and justifies the omission. The statement shall be submitted as a separate section in the HDE and identified in the table of contents. If the justification for the omission is not accepted by the agency, FDA will so notify the applicant.

(e) *Address for submissions and correspondence.* Copies of all original HDE's, amendments, supplements, and requests for extension, as well as any correspondence relating to an HDE, shall be sent or delivered to the Document Mail Center (HFZ-401), Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, § 814.104 was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 814.106 HDE amendments and resubmitted HDE's.

An HDE or HDE supplement may be amended or resubmitted upon an applicant's own initiative, or at the request of FDA, for the same reasons and in the same manner as prescribed for PMA's in § 814.37. The timeframes and extension of review times set forth in § 814.37 for PMA's shall also be applicable to HDE's.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, § 814.106 was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 814.108 Supplemental applications.

After FDA approval of an original HDE, an applicant shall submit supplements in accordance with the requirements for PMA's under § 814.39, except that a request for a new indication for use of a HUD shall comply with the requirements set forth in § 814.110.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, § 814.108 was stayed. This section contains information collection and recordkeeping requirements and will not become

effective until approval has been given by the Office of Management and Budget.

§ 814.110 New indications for use.

(a) An applicant seeking a new indication for use of a HUD approved under this subpart H shall obtain a new designation of HUD status in accordance with § 814.102 and shall submit an original HDE in accordance with § 814.104.

(b) An application for a new indication for use made under § 814.104 may incorporate by reference any information or data previously submitted to the agency under an HDE.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, in § 814.110, paragraph (a) was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 814.112 Filing an HDE.

(a) The filing of an HDE means that FDA has made a threshold determination that the application is sufficiently complete to permit substantive review. Within 45 days from the date an HDE is received by FDA, the agency will notify the applicant whether the application has been filed. FDA may refuse to file an HDE if any of the following applies:

(1) The application is incomplete because it does not on its face contain all the information required under § 814.104(c);

(2) FDA determines that there is a comparable device available (other than another HUD approved under this subpart or a device under an approved IDE) to treat or diagnose the disease or condition for which approval of the HUD is being sought; or

(3) The application contains an untrue statement of material fact or omits material information.

(b) The provisions contained in § 814.42(b), (c), and (d) regarding notification of filing decisions, filing dates, the start of the 180-day review period, and applicant's options in response to FDA refuse to file decisions shall apply to HDE's submitted under this subpart as well as to PMA's submitted under § 814.20.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, in § 814.112, paragraph (b) was stayed.

This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 814.114 Timeframes for reviewing an HDE.

Within 180 days after receipt of an HDE that is accepted for filing and to which the applicant does not submit a major amendment, FDA will send the applicant an approval order, an approvable letter, or a not approvable letter (under § 814.116), or an order denying approval (under § 814.118).

§ 814.116 Procedures for review of an HDE.

(a) *Substantive review.* FDA will begin substantive review of an HDE after the HDE is accepted for filing under § 814.112. FDA may refer an original HDE application to a panel on its own initiative, and shall do so upon the request of an applicant, unless FDA determines that the application substantially duplicates information previously reviewed by a panel. If the HDE is referred to a panel, the agency shall follow the procedures set forth under § 814.44.

(b) *Approval order.* FDA will issue to the applicant an order approving an HDE if none of the reasons in § 814.118 for denying approval of the application applies. FDA will approve an application on the basis of draft final labeling if the only deficiencies in the application concern editorial or similar minor deficiencies in the draft final labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed and upon the applicant submitting to FDA a copy of the final printed labeling before marketing. The notice of approval of an HDE will be published in the FEDERAL REGISTER in accordance with the rules and policies applicable to PMA's submitted under § 814.20. Following the issuance of an approval order, data and information in the HDE file will be available for public disclosure in accordance with § 814.9(b) through (h), as applicable.

(c) *Approvable letter.* FDA will send the applicant an approvable letter if the application substantially meets the requirements of this subpart and the

agency believes it can approve the application if specific additional information is submitted or specific conditions are agreed to by the applicant. The approvable letter will describe the information FDA requires to be provided by the applicant or the conditions the applicant is required to meet to obtain approval. For example, FDA may require as a condition to approval:

- (1) The submission of certain information identified in the approvable letter, e.g., final labeling;
- (2) Restrictions imposed on the device under section 520(e) of the act;
- (3) Postapproval requirements as described in subpart E of this part; and
- (4) An FDA inspection that finds the manufacturing facilities, methods, and controls in compliance with part 820 of this chapter and, if applicable, that verifies records pertinent to the HDE.

(d) *Not approvable letter.* FDA will send the applicant a not approvable letter if the agency believes that the application may not be approved for one or more of the reasons given in § 814.118. The not approvable letter will describe the deficiencies in the application and, where practical, will identify measures required to place the HDE in approvable form. The applicant may respond to the not approvable letter in the same manner as permitted for not approvable letters for PMA's under § 814.44(f).

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, in § 814.116, paragraph (b) was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 814.118 Denial of approval or withdrawal of approval of an HDE.

(a) FDA may deny approval or withdraw approval of an application if the applicant fails to meet the requirements of section 520(m) of the act or of this part, or of any condition of approval imposed by an IRB or by FDA, or any postapproval requirements imposed under § 814.126. In addition, FDA may deny approval or withdraw approval of an application if, upon the basis of the information submitted in the HDE or any other information before the agency, FDA determines that:

(1) There is a lack of a showing of reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(2) The device is ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(3) The applicant has not demonstrated that there is a reasonable basis from which to conclude that the probable benefit to health from the use of the device outweighs the risk of injury or illness, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment;

(4) The application or a report submitted by or on behalf of the applicant contains an untrue statement of material fact, or omits material information;

(5) The device's labeling does not comply with the requirements in part 801 or part 809 of this chapter;

(6) A nonclinical laboratory study that is described in the HDE and that is essential to show that the device is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations in part 58 of this chapter and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study;

(7) Any clinical investigation involving human subjects described in the HDE, subject to the institutional review board regulations in part 56 of this chapter or the informed consent regulations in part 50 of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected;

(8) The applicant does not permit an authorized FDA employee an opportunity to inspect at a reasonable time and in a reasonable manner the facilities and controls, and to have access to and to copy and verify all records pertinent to the application; and

(9) The device's HUD designation should be revoked in accordance with § 814.102(c).

(b) If FDA issues an order denying approval of an application, the agency will comply with the same notice and disclosure provisions required for PMA's under § 814.45(b) and (d), as applicable.

(c) FDA will issue an order denying approval of an HDE after an approvable or not approvable letter has been sent and the applicant:

(1) Submits a requested amendment but any ground for denying approval of the application under § 814.118(a) still applies;

(2) Notifies FDA in writing that the requested amendment will not be submitted; or

(3) Petitions for review under section 515(d)(3) of the act by filing a petition in the form of a petition for reconsideration under § 10.33 of this chapter.

(d) Before issuing an order withdrawing approval of an HDE, FDA will provide the applicant with notice and an opportunity for a hearing as required for PMA's under § 814.46(c) and (d), and will provide the public with notice in accordance with § 814.46(e), as applicable.

(e) Unless FDA otherwise determines that continued marketing under the HDE is inconsistent with the intent of section 520(m) of the act, FDA will not withdraw approval of an HDE solely because it is subsequently determined that the disease or condition for which the HUD is intended affects or is manifested in more than 4,000 people in the United States per year. However, this fact may serve as a basis for disapproving an extension request.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, in § 814.118, paragraph (d) was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 814.120 Requests for extension.

(a) *Eligibility.* In response to a request by the holder of an HDE, FDA may extend the HDE for an additional 18-month term. An exemption may be extended more than once, and may be extended after the expiration of the 5-

year period that began on October 24, 1996, as provided by section 520(m)(5) of the act. If the approval term for an HDE has lapsed, the HDE is ineligible for extension under this section and the applicant must cease marketing the device until a new HDE has been submitted and approved in accordance with this part.

(b) *Submission.* In order to avoid the risk of a lapse in marketing approval, the holder of an HDE wishing to obtain an extension shall submit such a request to FDA at least 90 days prior to the expiration of the HDE. A request for extension must be submitted in writing, together with a new, separately bound, request for HUD designation. The request for extension and the request for HUD designation shall be submitted to the Office of Device Evaluation, CDRH at the address specified for the submission of original HDE's (§814.104(e)), and the outside envelope should be plainly marked: "Request for Extension of HDE Approval." The submission shall state the applicant's name and address, the HDE number, and shall include the following information based upon the first 12 months of experience with the device following the most recent HDE approval or extension:

(1) An update of the information required under §814.102(a) in a separately bound volume;

(2) An update of the information required under §§814.104(c)(2), (c)(3), and (c)(5);

(3) The number of devices that have been shipped or sold since initial marketing approval under this subpart and, if the number shipped or sold exceeds 4,000, an explanation and estimate of the number of devices used per patient. If a single device is used on multiple patients, the applicant shall submit an estimate of the number of patients treated or diagnosed using the device together with an explanation of the basis for the estimate;

(4) Information describing the applicant's clinical experience with the device since the HDE was initially approved. This shall include safety information that is known or reasonably should be known to the applicant, medical device reports made pursuant to part 803 of this chapter, any data gen-

erated from postmarketing studies, and information (whether published or unpublished) that is known or reasonably expected to be known by the applicant that may affect an evaluation of the safety of the device or that may affect the statement of contraindications, warnings, precautions, and adverse reactions in the device labeling; and

(5) A summary of any changes made to the device in accordance with supplements submitted under §814.108.

(c) *Action.* Within 90 days of receipt of a request for an extension of an HDE that is submitted in accordance with this section, FDA will send the applicant either an approval order, approvable letter, a not approvable letter, or an order denying approval, applying the same criteria under this subpart as are applicable to the original HUD designation and HDE application. The effective date of an extension shall be the day the extension was granted or the day following the last effective day of the original HDE approval or the most recent extension, whichever is later. An extension request not acted upon by FDA within 90 days shall be deemed approved.

(d) *Waiver of final report.* An HDE holder seeking a request for extension under this section is exempt from the requirement of submitting a final report under §814.126(b).

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, in §814.120, paragraph (b) was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§814.122 Confidentiality of data and information.

(a) *Requirement for disclosure.* The "HDE file" includes all data and information submitted with or referenced in the HDE, any IDE incorporated into the HDE, any HDE amendment or supplement, any report submitted under §814.126, any master file, or any other related submission. Any record in the HDE file will be available for public disclosure in accordance with the provisions of this section and part 20 of this chapter.

(b) *Extent of disclosure.* Disclosure by FDA of the existence and contents of an HDE file shall be subject to the same rules that pertain to PMA's under § 814.9(b) through (h), as applicable.

§ 814.124 Institutional Review Board requirements.

(a) *IRB approval.* The HDE holder is responsible for ensuring that a HUD approved under this subpart is administered only in facilities having an Institutional Review Board (IRB) constituted and acting pursuant to part 56 of this chapter, including continuing review of use of the device. In addition, a HUD may be administered only if such use has been approved by the IRB located at the facility or by a similarly constituted IRB that has agreed to oversee such use and to which the local IRB has deferred in a letter to the HDE holder, signed by the IRB chair or an authorized designee.

(b) *Withdrawal of IRB approval.* A holder of an approved HDE shall notify FDA of any withdrawal of approval for the use of a HUD by a reviewing IRB within 5 working days after being notified of the withdrawal of approval.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, in § 814.124, paragraph (b) was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 814.126 Postapproval requirements and reports.

(a) An HDE approved under this subpart H shall be subject to the postapproval requirements and reports set forth under subpart E of this part, as applicable. In addition, medical device reports submitted to FDA in compliance with the requirements of part 803 of this chapter shall also be submitted to the IRB of record.

(b) In addition to the reports required under subpart E of this part, the holder of an approved HDE shall prepare and submit the following complete, accurate, and timely reports:

(1) *Final report.* Unless a request for extension is submitted in accordance with § 814.120, a final report shall be submitted no later than 90 days following the expiration of the period of mar-

keting approval. The final report shall include: An estimate of the number of patients who were treated or diagnosed with the device and the number of devices shipped or sold since initial marketing approval under this subpart H. (If the number of devices shipped or sold exceeds 4,000 per year, an explanation and estimate of the number of devices used per patient shall be included. Similarly, if a single device is used on multiple patients, the applicant shall submit an estimate of the number of patients treated or diagnosed using the device together with an explanation of the basis for the estimate.) The holder of the HDE shall also report information regarding retrieval or disabling of unused devices, a summary of results and conclusions with regard to clinical use of the device, and a summary of the medical device reports submitted under part 803 of this chapter. The report shall also contain a summary and bibliography of published and unpublished data, reports, and studies involving the device that are known to or that reasonably should be known to the applicant and were not previously submitted to FDA. If, after reviewing the summary and bibliography, FDA concludes that FDA needs a copy of the unpublished or published information, FDA will notify the applicant that copies shall be submitted.

(2) *Other.* An HDE holder shall, for the duration of the period that a HUD is approved for marketing, maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing IRB's, as well as any other information requested by a reviewing IRB or FDA.

EFFECTIVE DATE NOTE: At 61 FR 55741, Oct. 29, 1996, in § 814.126, paragraph (b)(1) was stayed. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

PART 820—QUALITY SYSTEM REGULATION (Eff. 6–1–97)

Subpart A—General Provisions

Sec.

820.1 Scope.

820.3 Definitions.

§ 820.1

820.5 Quality system.

Subpart B—Quality System Requirements

820.20 Management responsibility.

820.22 Quality audit.

820.25 Personnel.

Subpart C—Design Controls

820.30 Design controls.

Subpart D—Document Controls

820.40 Document controls.

Subpart E—Purchasing Controls

820.50 Purchasing controls.

Subpart F—Identification and Traceability

820.60 Identification.

820.65 Traceability.

Subpart G—Production and Process Controls

820.70 Production and process controls.

820.72 Inspection, measuring, and test equipment.

820.75 Process validation.

Subpart H—Acceptance Activities

820.80 Receiving, in-process, and finished device acceptance.

820.86 Acceptance status.

Subpart I—Nonconforming Product

820.90 Nonconforming product.

Subpart J—Corrective and Preventive Action

820.100 Corrective and preventive action.

Subpart K—Labeling and Packaging Control

820.120 Device labeling.

820.130 Device packaging.

Subpart L—Handling, Storage, Distribution, and Installation

820.140 Handling.

820.150 Storage.

820.160 Distribution.

820.170 Installation.

Subpart M—Records

820.180 General requirements.

820.181 Device master record.

820.184 Device history record.

820.186 Quality system record.

820.198 Complaint files.

21 CFR Ch. I (4–1–97 Edition)

Subpart N—Servicing

820.200 Servicing.

Subpart O—Statistical Techniques

820.250 Statistical techniques.

AUTHORITY: Secs. 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383).

SOURCE: 61 FR 52654, Oct. 7, 1996, unless otherwise noted.

EFFECTIVE DATE NOTE: At 61 FR 52654, Oct. 7, 1996, part 820 was revised, effective June 1, 1997. For the convenience of the user, the superseded text is set forth following the revised text.

Subpart A—General Provisions

§ 820.1 Scope.

(a) *Applicability.* (1) Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged. With respect to class I devices, design controls apply only to those devices listed in § 820.30(a)(2). This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance. Manufacturers of human blood and blood components are not subject to this part, but are subject to part 606 of this chapter.

(2) The provisions of this part shall be applicable to any finished device as

defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(3) In this regulation the term "where appropriate" is used several times. When a requirement is qualified by "where appropriate," it is deemed to be "appropriate" unless the manufacturer can document justification otherwise. A requirement is "appropriate" if nonimplementation could reasonably be expected to result in the product not meeting its specified requirements or the manufacturer not being able to carry out any necessary corrective action.

(b) *Limitations.* The quality system regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event that it is impossible to comply with all applicable regulations, both in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other generally applicable requirements.

(c) *Authority.* Part 820 is established and issued under authority of sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383). The failure to comply with any applicable provision in this part renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.

(d) *Foreign manufacturers.* If a manufacturer who offers devices for import into the United States refuses to permit or allow the completion of a Food and Drug Administration (FDA) inspection of the foreign facility for the purpose of determining compliance with this part, it shall appear for purposes of section 801(a) of the act, that the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, or servicing of any devices produced at such facility that are offered for import into the United States do not conform to the requirements of section 520(f) of the act and this part

and that the devices manufactured at that facility are adulterated under section 501(h) of the act.

(e) *Exemptions or variances.* (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance, (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1-800-638-2041 or 1-301-443-6597, FAX 301-443-8818.

(2) FDA may initiate and grant a variance from any device quality system requirement when the agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

(f) This part does not apply to distributors of cigarettes or smokeless tobacco as defined in part 897 of this chapter.

EFFECTIVE DATE NOTE: At 61 FR 44615, Aug. 28, 1996, in § 820.1, paragraph (f) was added, effective Aug. 28, 1997.

§ 820.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-903, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 321-394)). All definitions in section 201 of the act shall apply to the regulations in this part.

(b) *Complaint* means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

(c) *Component* means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.

(d) *Control number* means any distinctive symbols, such as a distinctive combination of letters or numbers, or

both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished devices can be determined.

(e) *Design history file (DHF)* means a compilation of records which describes the design history of a finished device.

(f) *Design input* means the physical and performance requirements of a device that are used as a basis for device design.

(g) *Design output* means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

(h) *Design review* means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

(i) *Device history record (DHR)* means a compilation of records containing the production history of a finished device.

(j) *Device master record (DMR)* means a compilation of records containing the procedures and specifications for a finished device.

(k) *Establish* means define, document (in writing or electronically), and implement.

(l) *Finished device* means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

(m) *Lot or batch* means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

(n) *Management with executive responsibility* means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.

(o) *Manufacturer* means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not

limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repackaging, or specification development, and initial distributors of foreign entities performing these functions.

(p) *Manufacturing material* means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.

(q) *Nonconformity* means the non-fulfillment of a specified requirement.

(r) *Product* means components, manufacturing materials, in-process devices, finished devices, and returned devices.

(s) *Quality* means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

(t) *Quality audit* means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.

(u) *Quality policy* means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.

(v) *Quality system* means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

(w) *Remanufacturer* means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

(x) *Rework* means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

(y) *Specification* means any requirement with which a product, process, service, or other activity must conform.

(z) *Validation* means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

(1) *Process validation* means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

(2) *Design validation* means establishing by objective evidence that device specifications conform with user needs and intended use(s).

(aa) *Verification* means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

§ 820.5 Quality system.

Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.

Subpart B—Quality System Requirements

§ 820.20 Management responsibility.

(a) *Quality policy.* Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

(b) *Organization.* Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.

(1) *Responsibility and authority.* Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.

(2) *Resources.* Each manufacturer shall provide adequate resources, in-

cluding the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.

(3) *Management representative.* Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:

(i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and

(ii) Reporting on the performance of the quality system to management with executive responsibility for review.

(c) *Management review.* Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.

(d) *Quality planning.* Each manufacturer shall establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met.

(e) *Quality system procedures.* Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.

§ 820.22 Quality audit.

Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of

deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.

§ 820.25 Personnel.

(a) *General.* Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.

(b) *Training.* Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.

(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.

(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

Subpart C—Design Controls

§ 820.30 Design controls.

(a) *General.* (1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

(2) The following class I devices are subject to design controls:

(i) Devices automated with computer software; and

(ii) The devices listed in the following chart.

Section	Device
868.6810	Catheter, Tracheobronchial Suction.
878.4460	Glove, Surgeon's.
880.6760	Restraint, Protective.
892.5650	System, Applicator, Radionuclide, Manual.
892.5740	Source, Radionuclide Teletherapy.

(b) *Design and development planning.* Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.

(c) *Design input.* Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

(d) *Design output.* Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

(e) *Design review.* Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a

design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).

(f) *Design verification.* Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

(g) *Design validation.* Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

(h) *Design transfer.* Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

(i) *Design changes.* Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

(j) *Design history file.* Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

Subpart D—Document Controls

§ 820.40 Document controls.

Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:

(a) *Document approval and distribution.* Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.

(b) *Document changes.* Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

Subpart E—Purchasing Controls

§ 820.50 Purchasing controls.

Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

(a) *Evaluation of suppliers, contractors, and consultants.* Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:

(1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.

(2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.

(3) Establish and maintain records of acceptable suppliers, contractors, and consultants.

(b) *Purchasing data.* Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with § 820.40.

Subpart F—Identification and Traceability

§ 820.60 Identification.

Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mixups.

§ 820.65 Traceability.

Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

Subpart G—Production and Process Controls

§ 820.70 Production and process controls.

(a) *General.* Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:

(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

(2) Monitoring and control of process parameters and component and device characteristics during production;

(3) Compliance with specified reference standards or codes;

(4) The approval of processes and process equipment; and

(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

(b) *Production and process changes.* Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to § 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with § 820.40.

(c) *Environmental control.* Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed.

(d) *Personnel.* Each manufacturer shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality. The manufacturer shall ensure that maintenance and other personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained individual.

(e) *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

(f) *Buildings.* Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mixups, and assure orderly handling.

(g) *Equipment.* Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

(1) *Maintenance schedule.* Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.

(2) *Inspection.* Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual(s) conducting the inspections, shall be documented.

(3) *Adjustment.* Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.

(h) *Manufacturing material.* Where a manufacturing material could reason-

ably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

(i) *Automated processes.* When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

§ 820.72 Inspection, measuring, and test equipment.

(a) *Control of inspection, measuring, and test equipment.* Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.

(b) *Calibration.* Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented.

(1) *Calibration standards.* Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If

no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

(2) *Calibration records.* The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

§ 820.75 Process validation.

(a) Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.

(b) Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.

(1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s).

(2) For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.

(c) When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.

Subpart H—Acceptance Activities

§ 820.80 Receiving, in-process, and finished device acceptance.

(a) *General.* Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.

(b) *Receiving acceptance activities.* Each manufacturer shall establish and

maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.

(c) *In-process acceptance activities.* Each manufacturer shall establish and maintain acceptance procedures, where appropriate, to ensure that specified requirements for in-process product are met. Such procedures shall ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented.

(d) *Final acceptance activities.* Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until:

(1) The activities required in the DMR are completed;

(2) the associated data and documentation is reviewed;

(3) the release is authorized by the signature of a designated individual(s); and

(4) the authorization is dated.

(e) *Acceptance records.* Each manufacturer shall document acceptance activities required by this part. These records shall include:

(1) The acceptance activities performed;

(2) the dates acceptance activities are performed;

(3) the results;

(4) the signature of the individual(s) conducting the acceptance activities; and

(5) where appropriate the equipment used. These records shall be part of the DHR.

§ 820.86 Acceptance status.

Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained

throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

Subpart I—Nonconforming Product

§ 820.90 Nonconforming product.

(a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.

(b) *Nonconformity review and disposition.* (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

Subpart J—Corrective and Preventive Action

§ 820.100 Corrective and preventive action.

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive ac-

tion. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.

Subpart K—Labeling and Packaging Control

§ 820.120 Device labeling.

Each manufacturer shall establish and maintain procedures to control labeling activities.

(a) *Label integrity.* Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and where appropriate use.

(b) *Labeling inspection.* Labeling shall not be released for storage or use until

a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR.

(c) *Labeling storage.* Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mixups.

(d) *Labeling operations.* Each manufacturer shall control labeling and packaging operations to prevent labeling mixups. The label and labeling used for each production unit, lot, or batch shall be documented in the DHR.

(e) *Control number.* Where a control number is required by § 820.65, that control number shall be on or shall accompany the device through distribution.

§ 820.130 Device packaging.

Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

Subpart L—Handling, Storage, Distribution, and Installation

§ 820.140 Handling.

Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.

§ 820.150 Storage.

(a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.

(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

§ 820.160 Distribution.

(a) Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.

(b) Each manufacturer shall maintain distribution records which include or refer to the location of:

- (1) The name and address of the initial consignee;
- (2) The identification and quantity of devices shipped;
- (3) The date shipped; and
- (4) Any control number(s) used.

§ 820.170 Installation.

(a) Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.

(b) The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation.

Subpart M—Records**§ 820.180 General requirements.**

All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(a) *Confidentiality.* Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.

(b) *Record retention period.* All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer.

(c) *Exceptions.* This section does not apply to the reports required by § 820.20(c) Management review, § 820.22 Quality audits, and supplier audit reports used to meet the requirements of § 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.

§ 820.181 Device master record.

Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with § 820.40. The DMR for each type of device shall include, or

refer to the location of, the following information:

(a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;

(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;

(c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;

(d) Packaging and labeling specifications, including methods and processes used; and

(e) Installation, maintenance, and servicing procedures and methods.

§ 820.184 Device history record.

Each manufacturer shall maintain device history records (DHR's). Each manufacturer shall establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this part. The DHR shall include, or refer to the location of, the following information:

(a) The dates of manufacture;

(b) The quantity manufactured;

(c) The quantity released for distribution;

(d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR;

(e) The primary identification label and labeling used for each production unit; and

(f) Any device identification(s) and control number(s) used.

§ 820.186 Quality system record.

Each manufacturer shall maintain a quality system record (QSR). The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including, but not limited to, the records required by § 820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with § 820.40.

§ 820.198 Complaint files.

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:

- (1) All complaints are processed in a uniform and timely manner;
- (2) Oral complaints are documented upon receipt; and
- (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 or 804 of this chapter, Medical Device Reporting.

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

(d) Any complaint that represents an event which must be reported to FDA under part 803 or 804 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by § 820.198(e), records of investigation under this paragraph shall include a determination of:

- (1) Whether the device failed to meet specifications;
- (2) Whether the device was being used for treatment or diagnosis; and
- (3) The relationship, if any, of the device to the reported incident or adverse event.

(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in

paragraph (a) of this section. The record of investigation shall include:

- (1) The name of the device;
- (2) The date the complaint was received;
- (3) Any device identification(s) and control number(s) used;
- (4) The name, address, and phone number of the complainant;
- (5) The nature and details of the complaint;
- (6) The dates and results of the investigation;
- (7) Any corrective action taken; and
- (8) Any reply to the complainant.

(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:

- (1) A location in the United States where the manufacturer's records are regularly kept; or
- (2) The location of the initial distributor.

Subpart N—Servicing

§ 820.200 Servicing.

(a) Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.

(b) Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with § 820.100.

(c) Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 or 804 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of § 820.198.

(d) Service reports shall be documented and shall include:

- (1) The name of the device serviced;

- (2) Any device identification(s) and control number(s) used;
- (3) The date of service;
- (4) The individual(s) servicing the device;
- (5) The service performed; and
- (6) The test and inspection data.

Subpart O—Statistical Techniques

§ 820.250 Statistical techniques.

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.

(b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

EFFECTIVE DATE NOTE: At 61 FR 52654, Oct. 7, 1996, part 820 was revised, effective June 1, 1997. For the convenience of the user, the superseded text is set forth as follows:

PART 820—GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES: GENERAL

Subpart A—General Provisions

- Sec.
- 820.1 Scope.
- 820.3 Definitions.
- 820.5 Quality assurance program.

Subpart B—Organization and Personnel

- 820.20 Organization.
- 820.25 Personnel.

Subpart C—Buildings

- 820.40 Buildings.
- 820.46 Environmental control.
- 820.56 Cleaning and sanitation.

Subpart D—Equipment

- 820.60 Equipment.
- 820.61 Measurement equipment.

Subpart E—Control of Components

- 820.80 Components.
- 820.81 Critical devices, components.

Subpart F—Production and Process Controls

- 820.100 Manufacturing specifications and processes.
- 820.101 Critical devices, manufacturing specifications, and processes.
- 820.115 Reprocessing of devices or components.
- 820.116 Critical devices, reprocessing of devices or components.

Subpart G—Packaging and Labeling Control

- 820.120 Device labeling.
- 820.121 Critical devices, device labeling.
- 820.130 Device packaging.

Subpart H—Holding, Distribution, and Installation

- 820.150 Distribution.
- 820.151 Critical devices, distribution, records.
- 820.152 Installation.

Subpart I—Device Evaluation

- 820.160 Finished device inspection.
- 820.161 Critical devices, finished device inspection.
- 820.162 Failure investigation.

Subpart J—Records

- 820.180 General requirements.
- 820.181 Device master record.
- 820.182 Critical devices, device master record.
- 820.184 Device history record.
- 820.185 Critical devices, device history record.
- 820.195 Critical devices, automated data processing.
- 820.198 Complaint files.

AUTHORITY: Secs. 501, 502, 515, 518, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360e, 360h, 360i, 360j, 371, 374).

SOURCE: 43 FR 31508, July 21, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 820.1 Scope.

The regulation set forth in this part describes current good manufacturing practices for methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of all finished devices intended for human use. The regulation is intended to assure that such devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act. Part 820 establishes

basic requirements applicable to finished devices, including additional requirements for critical devices. This regulation is not intended to apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidelines. Manufacturers of human blood and blood components are not subject to this part, but are subject to Part 606 of this chapter.

(a) *Authority.* This Part 820 is established and promulgated under authority of sections 501, 502, 518, 519, 520(f), and 701(a) of the act (21 U.S.C. 351, 352, 360h, 360i, 360j(f), and 371(a)). The failure to comply with any applicable provisions in Part 820 in the manufacture, packing, storage, or installation of a device renders the device adulterated under section 501(h) of the act. Such a device, as well as the person responsible for the failure to comply, is subject to regulatory action.

(b) *Limitations.* The current good manufacturing practice regulation in Part 820 supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event it is impossible to comply with applicable regulations both in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other regulations.

(c) *Applicability.* The provisions of Part 820 shall be applicable to any finished device, as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(d) *Exemptions or variances.* Any person who wishes to petition for an exemption or variance from any device good manufacturing practice requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in §10.30 of this chapter, the Food and Drug Administration's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Compliance Programs, Manufacturing Quality Assurance Branch (HFZ-332), 1390 Piccard Dr., Rockville, MD 20850; telephone 301-427-1128.

[43 FR 31508, July 21, 1978, as amended at 44 FR 75628, Dec. 21, 1979; 53 FR 11253, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

§ 820.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321–392)).

(b) *Audit* means a documented activity performed in accordance with written procedures on a periodic basis to verify, by exam-

ination and evaluation of objective evidence, compliance with those elements of the quality assurance program under review. “Audit” does not include surveillance or inspection activities performed for the purpose of conducting a quality assurance program or undertaking complaint investigations or failure analyses of a device.

(c) *Component* means any material, substance, piece, part, or assembly used during device manufacture which is intended to be included in the finished device.

(d) *Control number* means any distinctive combination of letters or numbers, or both, from which the complete history of the manufacture, control, packaging, and distribution of a production run, lot, or batch of finished devices can be determined.

(e) *Critical component* means any component of a critical device whose failure to perform can be reasonably expected to cause the failure of a critical device or to affect its safety or effectiveness.

(f) *Critical device* means a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user. Critical devices will be identified by the Commissioner after consultation with the Device Good Manufacturing Practice Advisory Committee authorized under section 520(f) of the act, and an illustrative list of critical devices will be available from the Center for Devices and Radiological Health, Food and Drug Administration.

(g) *Critical operation* means any operation in the manufacture of a critical device which, if improperly performed, can be reasonably expected to cause the failure of a critical device or to affect its safety or effectiveness.

(h) *Device history record* means a compilation of records containing the complete production history of a finished device.

(i) *Device master record* means a compilation of records containing the design, formulation, specifications, complete manufacturing procedures, quality assurance requirements, and labeling of a finished device.

(j) *Finished device* means a device, or any accessory to a device, which is suitable for use, whether or not packaged or labeled for commercial distribution.

(k) *Manufacturer* means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, or processes a finished device. The term does not include any person who only distributes a finished device.

(l) *Manufacturing material* means any material such as a cleaning agent, mold-release agent, lubricating oil, or other substance used to facilitate a manufacturing process

and which is not intended by the manufacturer to be included in the finished device.

(m) *Noncritical device* means any finished device other than a critical device.

(n) *Quality assurance* means all activities necessary to assure and verify confidence in the quality of the process used to manufacture a finished device.

[43 FR 31508, July 21, 1978, as amended at 53 FR 11253, Apr. 6, 1988]

§ 820.5 Quality assurance program.

Every finished device manufacturer shall prepare and implement a quality assurance program that is appropriate to the specific device manufactured and meets the requirements of this part.

Subpart B—Organization and Personnel

§ 820.20 Organization.

Each manufacturer shall have in place an adequate organizational structure and sufficient personnel to assure that the devices the manufacturer produces are manufactured in accordance with the requirements of this regulation. Each manufacturer shall prepare and implement quality assurance procedures adequate to assure that a formally established and documented quality assurance program is performed. Where possible, a designated individual(s) not having direct responsibility for the performance of a manufacturing operation shall be responsible for the quality assurance program.

(a) *Quality assurance program requirements.* The quality assurance program shall consist of procedures adequate to assure that the following functions are performed:

- (1) Review of production records;
- (2) Approval or rejection of all components, manufacturing materials, in-process materials, packaging materials, labeling, and finished devices; approval or rejection of devices manufactured, processed, packaged, or held under contract by another company;
- (3) Identifying, recommending, or providing solutions for quality assurance problems and verifying the implementation of such solutions; and

(4) Assuring that all quality assurance checks are appropriate and adequate for their purpose and are performed correctly.

(b) *Audit procedures.* Planned and periodic audits of the quality assurance program shall be implemented to verify compliance with the quality assurance program. The audits shall be performed in accordance with written procedures by appropriately trained individuals not having direct responsibilities for the matters being audited. Audit results shall be documented in written audit reports, which shall be reviewed by management having responsibility for the matters audited. Followup corrective action, including reaudit of deficient matters, shall be

taken when indicated. An employee of the Food and Drug Administration, designated by the Food and Drug Administration, shall have access to the written procedures established for the audit. Upon request of such an employee, a responsible official of the manufacturer shall certify in writing that the audits of the quality assurance program required under this paragraph have been performed and documented and that any required corrective action has been taken.

§ 820.25 Personnel.

Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all operations are correctly performed.

(a) *Personnel training.* All personnel shall have the necessary training to perform their assigned responsibilities adequately. Where training programs are necessary to assure that personnel have a thorough understanding of their jobs, such programs shall be conducted and documented. All employees shall be made aware of device defects which may occur from the improper performance of their specific jobs. Quality assurance personnel shall be made aware of defects and errors likely to be encountered as part of their quality assurance functions.

(b) *Personnel health and cleanliness.* Personnel in contact with a device or its environment shall be clean, healthy, and suitably attired where lack of cleanliness, good health, or suitable attire could adversely affect the device. Any personnel who, by medical examination or supervisory observation, appear to have a condition which could adversely affect the device shall be excluded from affected operations until the condition is corrected. Personnel shall be instructed to report such conditions to their supervisors.

Subpart C—Buildings

§ 820.40 Buildings.

Buildings in which manufacturing, assembling, packaging, packing, holding, testing, or labeling operations are conducted shall be of suitable design and contain sufficient space to facilitate adequate cleaning, maintenance, and other necessary operations. The facilities shall provide adequate space designed to prevent mixups and to assure orderly handling of the following: Incoming components; rejected or obsolete components; in-process components; finished devices; labeling; devices that have been reprocessed, reworked, or repaired; equipment; molds, patterns, tools, records, drawings, blueprints; testing and laboratory operations; and quarantined products.

§ 820.46 Environmental control.

Where environmental conditions at the manufacturing site could have an adverse effect on a device's fitness for use, these environmental conditions shall be controlled to prevent contamination of the device and to provide proper conditions for each of the operations performed pursuant to § 820.40. Conditions to be considered for control are lighting, ventilation, temperature, humidity, air pressure, filtration, airborne contamination, and other contamination. Any environmental control system shall be periodically inspected to verify that the system is properly functioning. Such inspections shall be documented.

§ 820.56 Cleaning and sanitation.

There shall be adequate written cleaning procedures and schedules to meet manufacturing process specifications. Such procedures shall be provided to appropriate personnel.

(a) *Personnel sanitation.* Washing and toilet facilities shall be clean and adequate. Where special clothing requirements are necessary to assure that a device is fit for its intended use, clean dressing rooms shall be provided for personnel.

(b) *Contamination control.* There shall be procedures designed to prevent contamination of equipment, components, or finished devices by rodenticides, insecticides, fungicides, fumigants, hazardous substances, and other cleaning and sanitizing substances. Such procedures shall be documented.

(c) *Personnel practices.* Where eating, drinking, and smoking by personnel could have an adverse effect on a device's fitness for use, such practices shall be limited to designated areas selected so as to avoid such an adverse effect.

(d) *Sewage and refuse disposal.* Sewage, trash, by-products, chemical effluents, and other refuse shall be disposed of in a timely, safe, and sanitary manner.

Subpart D—Equipment**§ 820.60 Equipment.**

Equipment used in the manufacturing process shall be appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, and cleaning.

(a) *Maintenance schedule.* Where maintenance of equipment is necessary to assure that manufacturing specifications are met, a written schedule for the maintenance, adjustment, and cleaning of equipment shall be developed and adhered to. Such schedule shall be visibly posted on or near each piece of equipment, or be readily available to personnel performing maintenance activities. A written record shall be maintained documenting when scheduled maintenance activities are performed.

(b) *Inspection.* Periodic documented inspections shall be made to assure adherence to applicable equipment maintenance schedules.

(c) *Adjustment.* Any inherent limitations or allowable tolerances shall be visibly posted on or near equipment requiring periodic adjustments, or be readily available to personnel performing these adjustments.

(d) *Manufacturing material.* Manufacturing material, including a cleaning agent, mold-release agent, lubricating oil, or other substance used on or in the manufacturing equipment or the device, shall be subsequently removed from the device or limited to a specified amount that does not adversely affect the device's fitness for use. There shall be written procedures for the use and removal of such manufacturing material. The removal of such manufacturing material shall be documented.

§ 820.61 Measurement equipment.

All production and quality assurance measurement equipment, such as mechanical, automated, or electronic equipment, shall be suitable for its intended purposes and shall be capable of producing valid results. Such equipment shall be routinely calibrated, inspected, and checked according to written procedures. Records documenting these activities shall be maintained. When computers are used as part of an automated production or quality assurance system, the computer software programs shall be validated by adequate and documented testing. All program changes shall be made by a designated individual(s) through a formal approval procedure.

(a) *Calibration.* Calibration procedures shall include specific directions and limits for accuracy and precision. There shall be provisions for remedial action when accuracy and precision limits are not met. Calibration shall be performed by personnel having the necessary education, training, background, and experience.

(b) *Calibration standards.* Where practical, the calibration standards used for production and quality assurance measurement equipment shall be traceable to the national standards of the National Bureau of Standards, Department of Commerce. If national standards are not practical for the parameter being measured, an independent reproducible standard shall be used. If no applicable standard exists, an in-house standard shall be developed and used.

(c) *Calibration records.* The calibration date, the calibrator, and the next calibration date shall be recorded and displayed, or records containing such information shall be readily available for each piece of equipment requiring calibration. A designated individual(s) shall maintain a record of calibration dates and of the individual performing each calibration.

Subpart E—Control of Components

§ 820.80 Components.

Components used in manufacturing shall be received, stored, and handled in a manner designed to prevent damage, mixup, contamination, and other adverse effects. Components shall be quarantined prior to acceptance or clearly identified as not yet accepted.

(a) *Acceptance of components.* There shall be a written procedure for acceptance of components. A designated individual(s) shall accept or reject components. A record shall be maintained of component acceptance and rejection. Upon receipt, each shipping container of components shall be visually examined for damage. Where deviations from component specifications could result in the device being unfit for its intended use, components shall be inspected, sampled, and tested for conformance to specifications.

(b) *Storage and handling of components.* If the quality or fitness for use of components deteriorates over time, the components shall be stored in a manner to facilitate proper stock rotation. Component control numbers or other identifications shall be easily viewable. All obsolete, rejected, or deteriorated components shall be clearly identified and segregated from accepted components. Records shall be maintained of the disposition of all obsolete, rejected, or deteriorated components.

§ 820.81 Critical devices, components.

In addition to the requirements of § 820.80, the following requirements apply to critical devices:

(a) *Acceptance of critical components.* There shall be written procedures for the accepting, sampling, testing, and inspecting of all lots of critical components to assure that critical components conform to specifications. The number of units sampled from each lot of critical components shall be based upon an acceptable statistical rationale, the past quality history of the supplier, and the quantity needed for analysis and reserve. Each lot of critical components shall be identified with a control number(s) upon receipt. The percentage of defective critical components for each lot and the percentage of lots rejected shall be recorded and identified by supplier name.

(b) *Critical component supplier agreement.* Where possible, the manufacturer shall secure from the critical component supplier a written agreement whereby the supplier agrees to notify the manufacturer of any proposed change in a critical component. Where such an agreement exists, the manufacturer shall not accept such a change until the manufacturer has determined the impact of the change on the finished device.

Subpart F—Production and Process Controls

§ 820.100 Manufacturing specifications and processes.

Written manufacturing specifications and processing procedures shall be established, implemented, and controlled to assure that the device conforms to its original design or any approved changes in that design.

(a) *Specification controls.* (1) Procedures for specification control measures shall be established to assure that the design basis for the device, components, and packaging is correctly translated into approved specifications.

(2) Specification changes shall be subject to controls as stringent as those applied to the original design specifications of the device. Such changes shall be approved and documented by a designated individual(s) and shall include the approval date and the date the change becomes effective.

(b) *Processing controls.* (1) Where deviations from device specifications could occur as a result of the manufacturing process itself, there shall be written procedures describing any processing controls necessary to assure conformance to specifications.

(2) All processing control operations shall be conducted in a manner designed to assure that the device conforms to applicable specifications.

(3) There shall be a formal approval procedure for any change in the manufacturing process of a device. Any approved change shall be communicated to appropriate personnel in a timely manner.

§ 820.101 Critical devices, manufacturing specifications, and processes.

In addition to the requirements of § 820.100, the following requirements apply to critical devices:

(a) *Critical operation performance.* Any critical operation shall be performed by a suitable designated individual(s) or suitable equipment and shall be verified.

(b) *Record of critical operation.* Any individual responsible for the performance of a critical operation shall record or reference that operation in the device history record as required in § 820.185.

§ 820.115 Reprocessing of devices or components.

(a) Reprocessing procedures shall be established, implemented, and controlled to assure that the reprocessed device or component meets the original, or subsequently modified and approved, specifications.

(b) Any device rejected during finished device inspection and later reprocessed shall be subject to another complete final inspection for any characteristic of the device which may be adversely affected by such reprocessing.

§ 820.116 Critical devices, reprocessing of devices or components.

In addition to the requirements of § 820.115, the following requirements apply to critical devices:

(a) *Reprocessing procedures.* There shall be written procedures for any reprocessing associated with the production of a critical device or component. These procedures shall prescribe the equipment to be used in reprocessing and shall include any special quality assurance methods or tests. The procedures shall be designed so that the reprocessed device or component meets the original, or subsequently modified and approved, specifications. The procedures shall be designed to prevent adulteration, e.g., because of material, structural, or molecular change in the device or component due to reprocessing. Special care shall be taken to assure that the device or component to be reprocessed is clearly identified and separated from like devices or components not to be reprocessed. When there is constant reprocessing of a device or component, a determination of the effect of the reprocessing upon the device or component shall be made and documented. There shall be a formal approval procedure for instituting a new, or altering an approved, reprocessing procedure.

(b) *Reprocessing control.* Any critical device or component subject to reprocessing procedures shall conform to the original, or subsequently modified and approved, specifications. Written testing and sampling procedures to assure such conformity shall be contained or referenced in the device master record. Any prior quality assurance check shall be repeated on the reprocessed device or component if the reprocessing could adversely affect any performance characteristic previously inspected.

Subpart G—Packaging and Labeling Control

§ 820.120 Device labeling.

There shall be adequate controls to maintain labeling integrity and to prevent labeling mixups.

(a) *Label integrity.* Labels shall be designed, printed, and applied so as to remain legible during the customary conditions of processing, storage, handling, distribution, and use. Labels and other labeling shall not be released to inventory until a designated individual has proofread samples of the labeling for accuracy.

(b) *Separation of operations.* Each labeling or packaging operation shall be separated physically or spatially in a manner designed to prevent mixups.

(c) *Area inspection.* Prior to the implementation of any labeling or packaging operation, there shall be an inspection of the area where the operation is to occur by a designated individual to assure that devices

and labeling materials from prior operations do not remain in the labeling or packaging area. Any such items found shall be destroyed, disposed of, or returned to storage prior to the onset of a new or different labeling or packaging operation.

(d) *Storage.* Labels and labeling shall be stored and maintained in a manner that provides proper identification and is designed to prevent mixups.

(e) *Labeling materials.* Labeling materials issued for devices shall be examined for identity and, where applicable, the correct expiration date, control number, storage instructions, handling instructions, and additional processing instructions. A record of such examination, including the date and person performing the examination, shall be maintained in the device history record.

§ 820.121 Critical devices, device labeling.

In addition to the requirements of § 820.120, the following requirements apply to critical devices:

(a) *Control number.* Labels issued for critical devices shall contain a control number.

(b) *Labeling check.* The signature of the individual who proofreads the labels and other labeling, and the date of the proofreading, shall be recorded.

(c) *Access restriction.* Access to the labels and other labeling shall be restricted to authorized personnel.

§ 820.130 Device packaging.

The device package and any shipping container for a device shall be designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

Subpart H—Holding, Distribution, and Installation

§ 820.150 Distribution.

There shall be written procedures for warehouse control and distribution of finished devices to assure that only those devices approved for release are distributed. Where a device's fitness for use or quality deteriorates over time, there shall be a system to assure that the oldest approved devices are distributed first.

§ 820.151 Critical devices, distribution records.

In addition to the requirements of § 820.150, adequate distribution records for critical devices shall include, or make reference to the location of: the name and address of the consignee, the name and quantity of devices, the date shipped, and the control number used. These records shall be retained as required by § 820.180(b).

§ 820.152 Installation.

Where a device is installed by the manufacturer or its authorized representative, the manufacturer or representative shall inspect the device after installation to assure that the device will perform as intended. Where a device is installed by a person other than the manufacturer or its authorized representative, the manufacturer shall provide adequate instructions and procedures for proper installation.

Subpart I—Device Evaluation**§ 820.160 Finished device inspection.**

There shall be written procedures for finished device inspection to assure that device specifications are met. Prior to release for distribution, each production run, lot or batch shall be checked and, where necessary, tested for conformance with device specifications. Where practical, a device shall be selected from a production run, lot or batch and tested under simulated use conditions. Sampling plans for checking, testing, and release of a device shall be based on an acceptable statistical rationale. Finished devices shall be held in quarantine or otherwise adequately controlled until released.

§ 820.161 Critical devices, finished device inspection.

In addition to the requirements of § 820.160, the following requirement applies to critical devices: A critical device or component which does not meet its performance specifications shall be investigated. A written record of the investigation, including conclusions and followup, shall be made. A critical device shall not leave the control of the manufacturer for distribution until all acceptance records and test results have been checked by a designated individual(s). Such individual(s) shall assure that all records and documentation required for the device history record are present and complete, and show that release of the device was consistent with the release criteria. Such individual(s) shall authorize, by signature, the release of the device for distribution.

§ 820.162 Failure investigation.

After a device has been released for distribution, any failure of that device or any of its components to meet performance specifications shall be investigated. A written record of the investigation, including conclusions and followup, shall be made.

Subpart J—Records**§ 820.180 General requirements.**

All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of the Food and

Drug Administration designated to perform inspections. Such records shall be available for review and copying by such employees. Except as specifically provided elsewhere, the following general provisions shall apply to all records required by this part.

(a) *Confidentiality.* Those records deemed confidential by the manufacturer may be marked to aid the Food and Drug Administration in determining whether information may be disclosed under the public information regulation in Part 20 of this chapter.

(b) *Record retention period.* All required records pertaining to a device shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer. Photostatic or other reproductions of records required by this part may be used.

§ 820.181 Device master record.

The device master record shall be prepared, dated, and signed by a designated individual(s). Any changes in the device master record shall be authorized in writing by the signature of a designated individual(s). Any approval forms shall be part of the device master record. The device master record for each type of device shall include, or refer to the location of, the following information:

(a) Device specifications including appropriate drawings, composition, formulation, and component specifications.

(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications.

(c) Quality assurance procedures and specifications including quality assurance checks used and the quality assurance apparatus used.

(d) Packaging and labeling specifications including methods and processes used.

§ 820.182 Critical devices, device master record.

In addition to the requirements of § 820.181, the device master record for a critical device shall include or refer to the location of the following information:

(a) *Critical components and critical component suppliers.* Full information concerning critical components and critical component suppliers, including the complete specifications of all critical components, the sources where they may be obtained, and written copies of any agreements made with suppliers under § 820.81(b).

(b) *Labels and labeling.* Complete labeling procedures for the individual device and copies of all approved labels and other labeling.

§ 820.184 Device history record.

A device history record shall be maintained to demonstrate that the device is manufactured in accordance with the device master record. The device history record shall include, or refer to the location of, the following information: The dates of manufacture, the quantity manufactured, the quantity released for distribution, and any control number used.

§ 820.185 Critical devices, device history record.

In addition to the requirements of § 820.184, the following requirements apply to critical devices: There shall be a critical device history record for each control number, which shall include complete information relating to the production unit. This record shall identify the specific label, labeling, and control number used for each production unit and shall be readily accessible and maintained by a designated individual(s). The device history record shall include, or refer to the location of, the following:

(a) *Component documentation.* The documentation of each critical component used in the manufacture of a device shall include:

(1) *Control number.* The control number designating each critical component or lot of critical components used in the manufacture of a device.

(2) *Acceptance record.* The acceptance record of the critical component, including acceptance date and signature of the recipient.

(b) *Record of critical operation.* The record of, or reference to, each critical operation, identifying the date performed, the designated individual(s) performing the operation and, when appropriate, the major equipment used.

(c) *Inspection checks.* The inspection checks performed, the methods and equipment used, results, the date, and signature of the inspecting individual.

§ 820.195 Critical devices, automated data processing.

When automated data processing is used for manufacturing or quality assurance purposes, adequate checks shall be designed and implemented to prevent inaccurate data output, input, and programming errors.

§ 820.198 Complaint files.

(a) Written and oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device shall be reviewed, evaluated, and maintained by a formally designated unit. This unit shall determine whether or not an investigation is necessary. When no investigation is made, the unit shall maintain a record that includes the reason and the name of the individual responsible for the decision not to investigate.

(b) Any complaint involving the possible failure of a device to meet any of its performance specifications shall be reviewed, evaluated, and investigated. Any complaint pertaining to injury, death, or any hazard to safety shall be immediately reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint file.

(c) When an investigation is made, a written record of each investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include the name of the device, any control number used, name of complainant, nature of complaint, and reply to complainant.

(d) Where the formally designated unit is located at a site separate from the actual manufacturing establishment, a duplicate copy of the record of investigation of any complaint shall be transmitted to and maintained at the actual manufacturing establishment in a file designated for device complaints.

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

Subpart A—General Provisions

Sec.

821.1 Scope.

821.2 Exemptions and variances.

821.3 Definitions.

821.4 Imported devices.

Subpart B—Tracking Requirements

821.20 Devices subject to tracking.

821.25 Device tracking system and content requirements: manufacturer requirements.

Subpart C—Additional Requirements and Responsibilities

821.30 Tracking obligations of persons other than device manufacturers: distributor requirements.

Subpart D—Records and Inspections

821.50 Availability.

821.55 Confidentiality.

821.60 Retention of records.

AUTHORITY: Secs. 301, 501, 502, 510, 515, 518, 519, 701, and 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, and 374).

SOURCE: 58 FR 43447, Aug. 16, 1993, unless otherwise noted.

Subpart A—General Provisions**§ 821.1 Scope.**

(a) The regulations in this part implement section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act) which requires the adoption of a method of device tracking by any person who registers under section 510 of the act and is engaged in the manufacture and distribution of devices the failure of which would be reasonably likely to have serious adverse health consequences if the devices are life-sustaining or life-supporting devices used outside of a device user facility or are permanently implantable devices. This part also applies to any other device that the Food and Drug Administration (FDA) designates as requiring a method of tracking to protect the public health. A device subject to this part either by statutory requirement or by FDA designation is referred to herein as a “tracked device.”

(b) These regulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities and licensed practitioners) and, ultimately, to any person for whom the device is intended is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act). Although these regulations do not preclude a manufacturer from involving outside organizations in that manufacturer's device tracking effort, the legal responsibility for complying with this part rests with manufacturers who must register under section 510 of the act, and that responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements.

(c) Each manufacturer of a tracked device shall implement a method of tracking devices by August 29, 1993.

(d) The primary burden for ensuring that the tracking system works rests upon the manufacturer. A manufac-

turer or any other person, including a distributor, final distributor, or multiple distributor, who distributes a device subject to tracking, who fails to comply with any applicable requirement of section 519(e) of the act or of this part, or any person who causes such failure, misbrands the device within the meaning of section 501(t)(2) of the act and commits a prohibited act within the meaning of sections 301(e) and 301(q)(1)(B) of the act.

(e) Any person subject to this part who permanently discontinues doing business is required to notify FDA at the time the person notifies any government agency, court, or supplier, and provide FDA with a complete set of its tracking records and information. However, if a person ceases distribution of a tracked device but continues to do other business, that person continues to be responsible for compliance with this part unless another person, affirmatively and in writing, assumes responsibility for continuing the tracking of devices previously distributed under this part. Further, if a person subject to this part goes out of business completely, but other persons acquire the right to manufacture or distribute tracked devices, those other persons are deemed to be responsible for continuing the tracking responsibility of the previous person under this part.

§ 821.2 Exemptions and variances.

(a) A manufacturer, importer, or distributor may seek an exemption or variance from one or more requirements of this part.

(b) A request for an exemption or variance shall be submitted in the form of a petition under § 10.30 of this chapter and shall comply with the requirements set out therein, except that a response shall be issued in 90 days. The Director or Deputy Directors, CDRH, or the Director, Office of Compliance, CDRH, shall issue responses to requests under this section. The petition shall also contain the following:

(1) The name of the device and device class and representative labeling showing the intended use(s) of the device;

(2) The reasons that compliance with the tracking requirements of this part is unnecessary;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that an effective tracking system is in place; and

(4) Other information justifying the exemption or variance.

(c) An exemption or variance is not effective until the Director, Office of Compliance and Surveillance, CDRH, approves the request under § 10.30(e)(2)(i) of this chapter.

(d) For petitions received under this section before August 29, 1993, FDA will, within 60 days, approve or disapprove the petition or extend the effective date of this part for the device that is the subject of the petition. Any extension that FDA grants to the effective date will be based upon the additional time FDA needs to complete its review of the petition.

[58 FR 43447, Aug. 16, 1993, as amended at 59 FR 31138, June 17, 1994]

§ 821.3 Definitions.

The following definitions and terms apply to this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, as amended.

(b) *Importer* means the initial distributor of an imported device who is required to register under section 510 of the act and § 807.20 of this chapter. “Importer” does not include anyone who only performs a service for the person who furthers the marketing, i.e., brokers, jobbers, or warehousemen.

(c) *Manufacturer* means any person, including any importer, repacker and/or relabeler, who manufactures, prepares, propagates, compounds, assembles, or processes a device or engages in any of the activities described in § 807.3(d) of this chapter.

(d) *Device failure* means the failure of a device to perform or function as intended, including any deviations from the device’s performance specifications or intended use.

(e) *Serious adverse health consequences* means any significant adverse experience related to a device, including device-related events which are life-threatening or which involve permanent or long-term injuries or illnesses.

(f) *Permanently implantable device* means a device that is intended to be

placed into a surgically or naturally formed cavity of the human body to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include any device which is intended and used for temporary purposes or which is intended for explantation.

(g) *Life-supporting or life-sustaining device used outside a device user facility* means a device which is essential, or yields information that is essential, to the restoration or continuation of a bodily function important to the continuation of human life that is intended for use outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. Physicians’ offices are not device user facilities and, therefore, devices used therein are subject to tracking if they otherwise satisfy the statutory and regulatory criteria.

(h) *Distributor* means any person who furthers the distribution of a device from the original place of manufacture to the person who makes delivery or sale to the ultimate user, i.e., the final or multiple distributor, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

(i) *Final distributor* means any person who distributes a tracked device intended for use by a single patient over the useful life of the device to the patient. This term includes, but is not limited to, licensed practitioners, retail pharmacies, hospitals, and other types of device user facilities.

(j) *Distributes* means any distribution of a tracked device, including the charitable distribution of a tracked device. This term does not include the distribution of a device under an effective investigational device exemption in accordance with section 520(g) of the act and part 812 of this chapter or the distribution of a device for teaching, law enforcement, research, or analysis as specified in § 801.125 of this chapter.

(k) *Multiple distributor* means any device user facility, rental company, or any other entity that distributes a life-sustaining or life-supporting device intended for use by more than one patient over the useful life of the device.

(l) *Licensed practitioner* means a physician, dentist, or other health care practitioner licensed by the law of the State in which he or she practices to use or order the use of the tracked device.

(m) Any term defined in section 201 of the act shall have the same definition in this part.

§ 821.4 Imported devices.

For purposes of this part, the importer of a tracked device shall be considered the manufacturer and shall be required to comply with all requirements of this part applicable to manufacturers. Importers must keep all information required under this part in the United States.

Subpart B—Tracking Requirements

§ 821.20 Devices subject to tracking.

(a) A manufacturer of any device the failure of which would be reasonably likely to have a serious adverse health consequence, that is either a life-sustaining or life-supporting device used outside of a device user facility or a permanently implantable device, or a manufacturer of any other device that FDA, in its discretion, designates for tracking, shall track that device in accordance with this part.

(b) Manufacturers have the responsibility to identify devices that meet the criteria for tracking and to initiate tracking. By way of illustration and to provide guidance, FDA has set out below a list of example devices it regards as subject to tracking under the criteria set forth in this regulation.

(1) Permanently implantable devices.

21 CFR	Classification
870.3450	Vascular graft prosthesis of less than 6 millimeters diameter
870.3460	Vascular graft prosthesis of 6 millimeters and greater diameter
(no cite)	Total temporomandibular joint prosthesis.
(no cite)	Glenoid fossa prosthesis.
(no cite)	Mandibular condyle prosthesis.
(no cite)	Interarticular disc prosthesis (interpositional implant).
870.3545	Ventricular bypass (assist) device
870.3610	Implantable pacemaker pulse generator
870.3680	Cardiovascular permanent pacemaker electrode
870.3800	Annuloplasty ring
870.3925	Replacement heart valve
(no cite)	Automatic implantable cardioverter/defibrillator
878.3720	Tracheal prosthesis
882.5820	Implanted cerebellar stimulator
882.5830	Implanted diaphragmatic/phrenic nerve stimulator

21 CFR	Classification
(no cite)	Implantable infusion pumps

(2) Life-sustaining or life-supporting devices used outside device user facilities

21 CFR	Classification
868.2375	Breathing frequency monitors (apnea monitors) (including ventilatory efforts monitors)
868.5895	Continuous ventilator
870.5300	DC-defibrillator and paddles

(c) FDA designates the following devices as subject to tracking. Manufacturers must track these devices in accordance with this part.

21 CFR	Classification
876.3350	Penile inflatable implant
878.3530	Silicone inflatable breast prosthesis
878.3540	Silicone gel-filled breast prosthesis
876.3750	Testicular prosthesis, silicone gel-filled
(no cite)	Silicone gel-filled chin prosthesis
(no cite)	Silicone gel-filled angel chik reflux valve
880.5725	Infusion pumps

(d) FDA, when responding to pre-market notification submissions and approving premarket approval applications, will notify the sponsor that FDA believes the device meets the criteria of section 519(e)(1) and therefore should be tracked. FDA will also, after notifying the sponsor, publish a notice in the FEDERAL REGISTER announcing that FDA believes a new generic type of device is subject to tracking and soliciting comment on FDA's position. If the device is a new generic type of device not already on the example list above, FDA will add it to this list.

[58 FR 43447, Aug. 16, 1993, as amended at 58 FR 43455, Aug. 16, 1993; 59 FR 15052, Mar. 31, 1994.]

§ 821.25 Device tracking system and content requirements: manufacturer requirements.

(a) A manufacturer of a tracked device shall adopt a method of tracking for each such type of device that it distributes that enables a manufacturer to provide FDA with the following information in writing for each tracked device distributed:

(1) Except as required by order under section 518(e) of the act, within 3 working days of a request from FDA, prior to the distribution of a tracked device to a patient, the name, address, and

telephone number of the distributor, multiple distributor, or final distributor holding the device for distribution and the location of the device;

(2) Within 10 working days of a request from FDA for life-sustaining or life-supporting devices used outside a device user facility that are intended for use by a single patient over the life of the device and permanent implants that are tracked devices, after distribution to or implantation in a patient:

(i) The lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, telephone number, and social security number (if available) of the patient receiving the device;

(iv) The date the device was provided to the patient;

(v) The name, mailing address, and telephone number of the prescribing physician;

(vi) The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(vii) If applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician; the date of the patient's death; or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(3) Except as required by order under section 518(e) within 10 working days of a request from FDA for life-sustaining or life-supporting devices used outside device user facilities that are intended for use by more than one patient and that are tracked devices, after the distribution of the device to the multiple distributor:

(i) The lot model number, batch number, serial number of the device or other identifier necessary to provide for effective tracking of the device;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, and telephone number of the multiple distributor;

(iv) The name, address, telephone number, and social security number (if available) of the patient using the device;

(v) The location of the device;

(vi) The date the device was provided for use by the patient;

(vii) The name, address, and telephone number of the prescribing physician; and

(viii) If and when applicable, the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(b) A manufacturer of a tracked device shall keep current records in accordance with its standard operating procedure of the information identified in paragraphs (a)(1), (a)(2) and (a)(3)(i) through (a)(3)(iii) of this section on each tracked device released for distribution for as long as such device is in use or in distribution for use.

(c) A manufacturer of a tracked device shall establish a written standard operating procedure for the collection, maintenance, and auditing of the data specified in paragraphs (a) and (b) of this section. A manufacturer shall make this standard operating procedure available to FDA upon request. A manufacturer shall incorporate the following into the standard operating procedure:

(1) Data collection and recording procedures, which shall include a procedure for recording when data which is required under this part is missing and could not be collected and the reason why such required data is missing and could not be collected;

(2) A method for recording all modifications or changes to the tracking system or to the data collected and maintained under the tracking system, reasons for any modification or change, and dates of any modification or change. Modification and changes included under this requirement include modifications to the data (including termination of tracking), the data format, the recording system, and the file maintenance procedures system; and

(3) A quality assurance program that includes an audit procedure to be run for each device product subject to

tracking, at not less than 6-month intervals for the first 3 years of distribution and at least once a year thereafter. This audit procedure shall provide for statistically relevant sampling of the data collected to ensure the accuracy of data and performance testing of the functioning of the tracking system.

(d) When a manufacturer becomes aware that a distributor, final distributor, or multiple distributor has not collected, maintained, or furnished any record or information required by this part, the manufacturer shall notify the FDA district office responsible for the area in which the distributor, final distributor, or multiple distributor is located of the failure of such persons to comply with the requirements of this part. Manufacturers shall have taken reasonable steps to obtain compliance by the distributor, multiple distributor, or final distributor in question before notifying FDA.

(e) A manufacturer may petition for an exemption or variance from one or more requirements of this part according to the procedures in § 821.2 of this chapter.

Subpart C—Additional Requirements and Responsibilities

§ 821.30 Tracking obligations of persons other than device manufacturers: distributor requirements.

(a) A distributor, final distributor, or multiple distributor of any tracked device shall, upon purchasing or otherwise acquiring any interest in such a device, promptly provide the manufacturer tracking the device with the following information:

(1) The name and address of the distributor, final distributor or multiple distributor;

(2) The lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;

(3) The date the device was received;

(4) The person from whom the device was received;

(5) If and when applicable, the date the device was explanted, the date of the patient's death, or the date the device was returned to the distributor,

permanently retired from use, or otherwise permanently disposed of.

(b) A final distributor, upon sale or other distribution of a tracked device for use in or by the patient, shall promptly provide the manufacturer tracking the device with the following information:

(1) The name and address of the final distributor;

(2) The lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;

(3) The name, address, telephone number, and social security number (if available) of the patient receiving the device;

(4) The date the device was provided to the patient or for use in the patient;

(5) The name, mailing address, and telephone number of the prescribing physician;

(6) The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(7) When applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician, the date of the patient's death, or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(c)(1) A multiple distributor shall keep written records of the following each time such device is distributed for use by a patient:

(i) The lot number, batch number, or model number, or serial number of the device or other identifier used by the manufacturer to track the device;

(ii) The name, address, telephone number, and social security number (if available) of the patient using the device;

(iii) The location of the device;

(iv) The date the device was provided for use by the patient;

(v) The name, address, and telephone number of the prescribing physician;

(vi) The name, address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(vii) When applicable, the date the device was permanently retired from